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SCREENING FOR DIABETES IN DENTAL SETTINGS

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Screening for Diabetes **In Dental Settings**

Kathryn Bould

PhD in Health Psychology

Abstract

Background: Screening for type 2 diabetes will potentially allow for early diagnosis and treatment. The current doctoral research focused on screening for diabetes in dental settings. The main objective of the research was to determine the impact of preliminary screening for diabetes using HbA1c information alongside a self-report questionnaire, in general dental practices on patient's health behaviours.

Methods: A systematic review of 18 studies was carried out to identify the best ways to communicate individualised risk information to improve screening uptake. Following the completion of the review, a longitudinal study based in two dental practices invited dental patients over 45 years old to participate in preliminary screening for diabetes. The study aimed to determine the uptake of preliminary screening in the dental practice environment using the self-report questionnaire and HbA1c test, and to determine the uptake of further diabetes testing by the GP following the receipt of a high HbA1c reading and a positive result on the self-report questionnaire. A qualitative element of the project involved interviewing participating patients (n=18) and dentists (n=6) to gain insight into their views and experiences of screening in this setting.

Results: The systematic review identified several important methods of risk communication (e.g. presenting in writing and in person) found to increase screening participation or its psychological predictors. These were used to inform the next stage of the research,

The longitudinal study indicated that of 520 dental patients taking part, half were found to have an increased level of risk of developing diabetes in the next ten years, based on at least one screening measure looking at personalised diabetes risk, and were advised to seek a diagnostic blood test from their GP. Sixty percent of those referred to their GP following the personalised diabetes risk communication, followed the advice and did so; those who had received two positive screening tests as opposed to just one, were three times more likely to make contact with their GP. When assessing whether certain psychological variables can predict and explain uptake of further testing by the GP, fear of diabetes and vulnerability to developing diabetes were found to be able to explain why some patients made contact with their GP whereas severity, intention, and self efficacy for example, were not associated with attendance at the GP. The qualitative data revealed that dentists and patients both reported positive experiences and patients offered explanations as to why they had or had not contacted their GP for further testing.

Conclusion: the set of studies demonstrated a well-tolerated and largely acceptable personalised diabetes risk screening method, with more than half of those recommended to do so, following advice to seek further diagnostic tests.

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Abbreviations

ADA	American Diabetes Association
SCM	Social Cognition Model
T1D	Type 1 Diabetes
T2D	Type 2 Diabetes
GDP	General Dental Practice/Practitioner
GP	General Practitioner
EPPM	Extended Parallel Process Model
FINDRISC	Finnish Diabetes Risk Score
ADDITION	Anglo-Danish-Dutch Study in General Practice of Intensive Treatment and Complication Prevention in Type 2 Diabetic Patients Identified by Screening
BMI	Body Mass Index
OGTT	Oral Glucose Tolerance Test
HbA1c	Glycated Haemoglobin
MeSH	medical subject heading
IGT	Impaired Glucose Tolerance
FPG	Fasting Plasma Glucose
FBG	Fasting Blood Glucose
RCT	Randomised Controlled Trial
OR	Odds Ratio
WHO	World Health Organisation
CRC	Colorectal cancer

Chapter 1

Executive Summary

This thesis describes a series of studies which explore screening for diabetes in a dental setting and the effect that screening has on an individual's subsequent decision to receive diagnostic testing.

The main objective of this thesis was to investigate use of a self-report screening measure and glycated haemoglobin A1c (HbA1c) information as preliminary screening tools for possible diabetes in general dental practice, and the affect this has on patients' health behaviour.

In particular, the following research questions (RQ) were set.

1. What is the most effective way to communicate individualised risk information to increase screening participation or its psychological predictors?
2. What proportion of dental patients accept an offer to be screened for type 2 diabetes in a primary care dental setting?
3. What is the risk of type 2 diabetes in primary care dental patients as assessed through self-report and physiological measures?
4. What is the effect of personalised diabetes risk communication on subsequent health behaviours?
5. What is the psychological profile of patients at risk of diabetes?
6. To what extent do psychological variables predict post-screening further testing or health behaviours?
7. What are patients' and dentists' views on screening for diabetes in dental settings, and can this help to further explain post-screening further testing or health behaviours?

Chapter 2 presents the background to the project and describes in detail the existing literature on what diabetes is, the prevalence of diabetes, through to how it is diagnosed and treated.

The debate of the worth of diabetes screening is then discussed, followed by the psychological effect of health screening and the psychological predictors of screening participation. Subsequently, the methods of diabetes screening are explored and research investigating various settings as a suitable place for diabetes screening are described. From

this, it is argued that diabetes screening within a dental setting is a viable option that needs to be explored further.

Chapter 3 details a systematic literature review that explored RQ1 - What is the most effective way to communicate individualised risk information to increase screening participation or its psychological predictors? A search of five databases was conducted to identify randomised controlled trials (RCTs) that examined the effect of individualised risk communication interventions on screening uptake or its psychological predictors. A total of twenty-one articles met the inclusion criteria, reporting eighteen studies. These studies were then reviewed systematically to determine the effectiveness of these interventions which is fully described in chapter 3.

Chapter 4 provides a detailed account of the methods employed in the empirical studies that were conducted within this doctoral research. It describes the methods for two quantitative studies and one qualitative study and outlines how the methodology was considered and then adopted in order to answer RQ 2-7.

Chapter 5 describes the first of two quantitative studies conducted. The study described in this chapter addresses RQ 2-4, and explains the proportion of dental patients who took part in the screening programme offered to them at their dental appointment. It also explains the risk of diabetes in these dental patients as assessed through a self-report risk questionnaire and a finger prick blood test. Finally, it describes the effect of these screening tests on subsequent diagnostic test follow-up behaviour.

Chapter 6 then goes on to describe the second quantitative study addressing RQ 5 and 6. After assessing the psychological profile of those found to be at risk of diabetes from the screening tests conducted, the chapter describes the extent to which psychological constructs are able to explain why some dental patients made contact with their GP for a diagnostic test.

Chapter 7 describes the qualitative study exploring dental patients and dental practitioner's views on screening for diabetes in the dental setting. Additionally, this work probed further into the findings of the quantitative studies and explored why some dental patients contacted their GP for a diagnostic test, whilst other did not, from the patient perspective.

Chapter 8, the final chapter in this thesis provides a detailed discussion of the topic of screening for diabetes in the dental setting following a brief summary of the findings from the studies conducted for this thesis and their contribution to the existing literature. It discusses

the practicalities of conducting diabetes screening as demonstrated in the current studies, as well as the methodological strengths and limitations of the procedure adopted in these studies. Finally, the chapter makes suggestions for future research that are needed before clinical recommendations can be made.

Chapter 2

Introduction and Literature Review

The studies included in this thesis look at the effect of preliminary screening for diabetes in dental settings on subsequent diabetes testing behaviour. Therefore, this introductory chapter outlines and describes diabetes, how it is identified, treated and managed by the individual. The chapter introduces and discusses the debate on screening for the condition to date, and why or why not it is recommended. The case for diabetes screening is put forward to support the rationale for the set of studies that follow in this thesis. When describing the effects of diabetes on a person's health, the discussion is weighted toward the effects on a person's oral health due to the nature of the focus of the doctoral studies, therefore when describing research looking at screening for diabetes, and where this might take place, there is a focus on research which has been conducted within the dental setting in order to investigate the potential for further study in this setting. Both dentist and dental patients' views about diabetes screening within the dental setting has been studied, therefore this research has also been considered in this introductory chapter.

What is Diabetes?

Diabetes mellitus comprises a heterogeneous group of disorders characterised by high blood glucose levels. Four major types of diabetes have been defined:

- insulin- dependent diabetes; now known as type 1 diabetes mellitus (T1D; (Mendosa, 2010);
- non-insulin- dependent diabetes mellitus, also now known as type 2 diabetes (T2D; (Mendosa, 2010);
- gestational diabetes mellitus (GDM); and
- diabetes secondary to other conditions (Harris, 1995).

These are each outlined below. Impaired glucose tolerance ('pre-diabetes') is also considered.

In T1D, the cause is an absolute deficiency of insulin secretion. Insulin is a hormone which works as a chemical messenger that helps the body use the glucose in the blood to give the body energy. When the body does not produce insulin, the body cannot use glucose to provide energy and so it tries to get it from elsewhere and starts to break down stores of fat and protein instead. Because the body does not use the glucose, it ends up passing into the

urine. Individuals at increased risk of developing this type of diabetes can often be identified by serological evidence of an autoimmune pathologic process occurring in the pancreatic islets or by genetic markers.

In the much more prevalent category, T2D, the cause is a combination of resistance to insulin action and an inadequate compensatory insulin secretory response (Burggraaf & Castro Cabezas, 2017). The result is often hyperglycaemia; a high level of blood glucose, a consequence of what happens when the body has too little insulin or when the body cannot use insulin properly. In T2D, a degree of hyperglycaemia enough to cause pathologic and functional changes in various target tissues, but without clinical symptoms, may be present for a long period of time before diabetes is detected. During this asymptomatic period, it is possible to demonstrate an abnormality in carbohydrate metabolism by measurement of plasma glucose in the fasting state or after a challenge with an oral glucose load (Expert Committee On The Diagnosis And Classification Of Diabetes Mellitus, 2002; Sami, Ansari, Butt, & Hamid, 2017).

GDM is defined as glucose intolerance that is first diagnosed in pregnancy (Eades, Cameron, & Evans, 2017). In some women, GDM occurs because the body cannot produce enough insulin to meet the extra needs of pregnancy. In other women, GDM may be found during the first trimester of pregnancy. GDM is also associated with an increased risk of complications for mother and child during pregnancy and birth (Horvath et al., 2010). Women with a history of GDM are at high risk for developing T2D. In studies with long periods of follow up, diabetes incidence of up to 70% has been reported (Kasher-Meron & Grajower, 2017).

Diabetes can also be associated with certain conditions or syndromes, where hyperglycaemia occurs in relation to other disease states such as pancreatic diseases, drug or chemical-induced diabetes, insulin-receptor disorders and certain genetic syndromes (American Diabetes Association, 1992; Penfornis & Kury-Paulin, 2006).

Impaired glucose tolerance (IGT) is where there is an abnormality in glucose levels, often referred to as an intermediate stage between normal glucose homeostasis and overt T2D (Di Pino, Urbano, Piro, Purrello, & Rabuazzo, 2016). Also known as Pre-diabetes, it occurs when glucose levels are higher than normal but not high enough for the person to be diagnosed as having diabetes, yet indicating the relatively high risk for the future development of diabetes. Having prediabetes causes no symptoms, and has been shown to put a person at risk of

having heart disease (Nathan et al., 2007). Pre-diabetes is of public health importance. This is because the risk of cardiovascular disease (CVD) is increased in people with prediabetes compared with people with normal glucose tolerance, and because many people with pre-diabetes will go on to develop diabetes. In terms of absolute numbers of heart attacks, pre-diabetes is a greater problem than diabetes, because, although the risk of heart disease is somewhat higher with diabetes, there are far more people with pre-diabetes than with undiagnosed diabetes (Waugh, Shyangdan, Taylor-Phillips, Suri, & Hall, 2013).

Risk factors

Risk factors in the development of diabetes include; obesity (a body mass index higher than 27 kilograms per square metre), a high-risk ethnic background (such as African-American or Asian), hypertension, high-density lipoprotein level lower than 35 milligrams per decilitre or a triglyceride level higher than 250 mg/dL, a first-degree relative with diabetes, history of gestational diabetes or delivery of a baby weighing more than nine pounds, impaired glucose tolerance or impaired fasting glycaemia (history of blood sugar level between 110 and 126 mg/dL), and a history of vascular disease or polycystic ovarian disease (Robertson, Drexler, & Vernillo, 2003). T2D is associated with irreversible risk factors such as age, genetics, race, and ethnicity and reversible factors such as diet, physical activity and smoking ((Sami et al., 2017). T2D is considered preventable; there is strong randomised trial evidence that intervention either by pharmacological or lifestyle methods in patients with pre-diabetes, can reduce risk of progression to T2D (Diabetes Prevention Program Research, 2002; Gillies et al., 2007)

Diabetes Prevention

Studies indicate T2D can also be prevented in high-risk individuals through lifestyle modification, pharmacologic interventions, and bariatric surgery, however, the translation of this research to a population level, especially finding the most effective methods of preventing T2DM in various societies and cultural settings is challenging, but is a crucial priority (Portero McLellan, Wyne, Villagomez, & Hsueh, 2014).

Findings from observational and experimental studies now provide consistent evidence that reducing and frequently breaking up prolonged sitting with light-intensity physical activities and standing may be practical strategies for improving T2D prevention and management (Dempsey, Owen, Yates, Kingwell, & Dunstan, 2016).

A recent systematic review looking at diabetes prevention sought to answer the following question. What is the efficacy of preventive interventions (lifestyle and/or metformin) in those identified as high risk by screening (Barry et al., 2017)? A meta-analysis showed that lifestyle interventions reduced the relative risk of developing diabetes by 31% (95% confidence interval 15% to 44%) if the intervention lasted six months to two years. This translates to 69 (95% confidence interval 56 to 85) out of 1000 people in the lifestyle intervention group developing diabetes compared with 100 out of 1000 without the intervention, or a number needed to treat (NNT) of 33 (95% confidence interval 23 to 67). Lifestyle interventions lasting three to six years showed a 37% (28% to 46%) reduction in relative risk, equating to 151 out of 1000 people in the lifestyle intervention group developing diabetes compared with 239 of 1000 in the control group (NNT 12). The overall relative risk reduction of developing diabetes after lifestyle interventions was 36%. Because of the small number of follow-up studies it is difficult to assess the reduction in risk of diabetes after the completion of lifestyle interventions.

Meta-analysis evaluating the impact of metformin showed a relative risk reduction of 26% (95% confidence interval 16% to 35%) while participants were taking this drug, translating to 218 (95% confidence interval 192 to 248) out of 1000 developing diabetes while taking metformin compared with 295 of 1000 not receiving this drug (NNT 14 (95% confidence interval 10 to 22)). The benefits of metformin were assessed at the end of the trial periods once the participants had been taking the drug for a specified length of time. There were no follow-up studies examining for persistence of benefit once metformin had been discontinued, but the authors reported the US DPP study which had shown some improvements in reduction in incidence of diabetes with long term metformin use.

In conclusion, both individually targeted lifestyle interventions and metformin have been found to have some efficacy in preventing or delaying the onset of T2D, though the protective effect of the lifestyle interventions is greatest in longer interventions (three to six years) (Barry et al., 2017).

A systematic review on the cost-effectiveness of lifestyle modification interventions showed that interventions targeting adult subjects at high risk for diabetes were cost-effective despite different assumptions regarding disease progression and variations in the delivery of these interventions (Alouki et al., 2016). The results of this systematic review are consistent with conclusions of former reviews, confirming the importance of lifestyle interventions

combining diet and physical activity to prevent diabetes in at-risk population groups. However, the authors believed that lifestyle interventions should be further stressed as an effective strategy to prevent or delay diabetes (Alouki et al., 2016).

Symptoms

Before diabetes is diagnosed, the main symptoms of undiagnosed diabetes can include; more frequent urination, especially at night, increased thirst, extreme tiredness, unexplained weight loss, genital itching or regular episodes of thrush, slow healing of cuts and wounds, and blurred vision (Clark, Fox, & Grandy, 2007). These signs and symptoms of diabetes are often disregarded because of the chronic progression of the disease. People do not consider this as a serious problem because unlike many other diseases the consequences of hyperglycaemia are not manifested immediately and are not that obviously debilitating (Ramachandran, 2014). In T1D the signs and symptoms are usually very obvious and develop very rapidly, typically over a few weeks (Atkinson & Eisenbarth, 2001). The symptoms are quickly relieved once the diabetes is treated and under control (Daneman, 2006; WHO, 2016). In T2D the signs and symptoms may not be so obvious, as the condition develops slowly over a period of years and may only be picked up during a routine medical check-up. Symptoms that are mild or have gradual development could also remain unnoticed (Ramachandran, 2014).

Prevalence of Diabetes

The global prevalence of diabetes in adults has been increasing over recent decades (Ogurtsova et al., 2017). Previously it had been reported that the number was increasing due to population growth, aging, urbanization, and increasing prevalence of obesity and physical inactivity (Wild, Roglic, Green, Sicree, & King, 2004). Most recently, in addition to the reported increase, it has also been reported that the dramatic increase in diabetes has been seen to have occurred in all countries, and in rural as well as urban areas (Ogurtsova et al., 2017).

Accurate global, regional, and country-level estimates and projections of diabetes prevalence are necessary for prevention and treatment strategies to be planned and monitored. T2D is much more common than T1D (BeLue et al., 2009). T2D accounts for around 90% of all diabetes worldwide (Kahn, 1998). Reports of T2D in children – previously rare – have increased worldwide (Hsia et al., 2009). In some countries, it accounts for almost half of newly diagnosed cases in children and adolescents (WHO, 2014). In a recent review by the

International Diabetes Federation, it was estimated that in 2015 there were 415 million people with diabetes aged 20–79 years, 5.0 million deaths attributable to diabetes, and a total global health expenditure due to diabetes of 673 billion US dollars. The number of people with diabetes aged 20–79 years was predicted to rise to 642 million by 2040 (Ogurtsova et al., 2017).

The prevalence of diabetes in the UK was estimated to be approximately 400,000 people with T1D and 3.4 million people with T2D (Hex, Bartlett, Wright, Taylor, & Varley, 2012).

Research conducted more recently has reported that since 1996, the number of people diagnosed with diabetes in the UK has more than doubled, from 1.4 million to almost 3.5 million. In 2015, over 2.9 million people were diagnosed with diabetes in England alone, 90% of whom have T2D (Holden et al., 2017). Using Office for National Statistics projections, it has been estimated that in the UK, the prevalence of T1D will rise to approximately 650,000 people and over 5.6 million people with T2D by 2035.

Diagnosis of Diabetes

Different biomarkers have been used to define when diabetes is present, including fasting plasma glucose (FPG), 2-h plasma glucose in an oral glucose tolerance test (2hOGTT), and, more recently, HbA1c (NCD Risk Factor Collaboration, 2015).

Several recognised tests that are used to *diagnose* diabetes are described below.

- *Fasting plasma glucose* - measures plasma, or blood, glucose levels after a person has fasted (Harris, 1995).

- *Random capillary blood glucose* – this test is the most convenient way to reach out to a large number of people (Somannavar, Ganesan, Deepa, Datta, & Mohan, 2009). However, although it is an established diagnostic criterion for diabetes, it is very insensitive, requiring diabetes to be in poor glycaemic control (Saudek et al., 2008). Therefore, this test may well not effectively identify pre-diabetes.

- *Oral glucose tolerance test* - is used to determine whether the body has difficulty metabolising the intake of sugar/carbohydrate. The patient is asked to take a glucose drink and their blood glucose level is measured before and at intervals after the sugary drink is

taken. The oral glucose tolerance test (OGTT) is costly and time-consuming, but is seen as the gold-standard test (Olson et al., 2010; Phillips, 2012).

- *HbA1c* - The A1C test is universally considered one of the best, if not the best, measure of the quality of healthcare provided to people with diabetes (Kahn, 2011). The most recent measure used in diagnosing diabetes, HbA1c testing does not require a person to fast and therefore does not need to be restricted to certain times of the day (Bloomgarden, 2009). The WHO Consultation in 2009 concluded that HbA1c can be used as a diagnostic test for diabetes, provided that stringent quality assurance tests are in place and assays are standardised to criteria aligned to the international reference values, and there are no conditions present which preclude its accurate measurement (WHO, 2011).

The latest guidelines recommended for a diagnosis of diabetes by WHO (WHO, 2006) and ADA (ADA, 2012) are:

- A fasting plasma glucose (FPG) level of ≥ 126 mg/dl (7.0 mmol/l) or
- Symptoms (such as polyuria, polydipsia, unexplained weight loss) and
- A casual plasma glucose/ random plasma glucose level ≥ 200 mg/dl (11.1 mmol/l) or
- A plasma glucose level of ≥ 200 mg/dl (11.1 mmol/l) two hours after a 75g glucose load, or
- HbA1c value of $\geq 6.5\%$.

Once the diagnosis is confirmed, an attempt is made to classify the type of diabetes. Distinction between the two major types of diabetes, that being T1D and T2D, can be difficult. However, signs and symptoms such as, an acute onset, onset at an early age, rapid weight loss and ketonuria (ketones present in urine), generally favour the diagnosis of T1D. Factors favouring a diagnosis of T2D usually include the absence of classical symptoms of diabetes and onset during later life at an older age (WHO, 1994, 2016).

Criteria have also been set for those considered to have prediabetes:

- Impaired fasting glucose (IFG) (fasting plasma glucose level of 100 - 125mg/dl (5.6 - 6.9mmol/l); or
- Impaired glucose tolerance (IGT) (two hours after taking the oral glucose tolerance test

(OGTT): 140 mg/dl - 199 mg/dl (7.8 - 11.0 mmol/l); or
-HbA1c value of 5.7 - 6.4%.

Management of diabetes

Diabetes is not a curable disease. Once diabetes is detected and has been diagnosed, the main aim for both the patient and healthcare provider is to ensure tight glycaemic control by means of lifestyle modification and pharmacological therapy, in order to prevent the development of diabetes-related complications (Chatterjee & Davies, 2015). Treatment after early detection of T2D has been said to yield benefits superior to those obtained when treatment is delayed (Engelgau, Narayan, & Herman, 2000). The Diabetes Control and Complications Trial (DCCT) in T1D and the United Kingdom Diabetes Prospective Study (UKPDS) in T2D have shown that intensive glycaemic control improves patient outcomes especially for microvascular complications (Holman, Paul, Bethel, Matthews, & Neil, 2008; Nathan et al., 2005).

Diet control is the first step in individuals with Type 2 diabetes, reducing the intake of refined sugar and foods high in fat. Weight loss and exercise may also be advocated in order to reduce body fat. Oral hypoglycaemic agents such as metformin hydrochloride, are used when dietary measures are unsuccessful. These aim to promote insulin release from the pancreas, encourage insulin uptake in the target organs and suppress appetite (DeFronzo, 2009). Insulin therapy is required in T1D, severely uncontrolled T2D and for T2D patients with decreased insulin production. Modern insulin therapy combines the use of short acting, rapid onset insulin with a longer acting form, so that glucose levels are maintained with minimal peaks and troughs through the day (Bjelland, Bray, Gupta, & Hirscht, 2002). Hypoglycaemia and weight gain remain the two significant side effects of intensive insulin therapy. Reluctance to commence insulin therapy is an issue in treatment, due to factors such as fear of hypoglycaemia, weight gain and needle phobia in patients and clinical inertia on the part of healthcare professionals (Chatterjee & Davies, 2015).

Structured education programmes are considered essential to improve patient motivation, self-management skills and empowerment (Chatterjee & Davies, 2015). To ensure appropriate management, the basic knowledge and skills should be

acquired by the patient and their family, and the health care team should work closely with the patient to achieve this objective and to promote self-care. The person with diabetes should also be involved in setting therapeutic targets for weight, blood pressure and blood sugar control in order to self-manage the condition (WHO, 2016). The teaching of carbohydrate counting principles and insulin management skills in the Dose Adjustment for Normal Eating (DAFNE) programme to patients with T1D has been shown to improve quality of life and glycaemic control and is also cost-effective (Cooke et al., 2013). Structured education on reduced calorie intake and increased physical activity for T2D is provided through self-management and lay educator support in the Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) programme. It has demonstrated significant improvement in weight loss, smoking rates, depression levels and cardiovascular risk scores (Davies et al., 2008). Self-management training is required according to a systematic review by Norris and colleagues. In a review of 72 studies, evidence supported the effectiveness of self-management training in T2D, particularly in the short term, with positive effects on knowledge, frequency and accuracy of blood glucose, dietary habits, and glycaemic control (Norris, Engelgau, & Narayan, 2001). Diabetes necessitates that a person be proficient in self-management skills; and in order for people to learn the skills necessary to be effective at self-managing their condition, diabetes self-management education is critical at laying the foundation with ongoing support to maintain the benefits and progress made during education. The ADA posit that all individuals with diabetes receive diabetes self-management education and support at the time of diagnosis and as needed thereafter (Powers et al., 2015).

Diabetes Complications

The characteristic metabolic disorder in diabetes is hyperglycaemia, and when poorly controlled is the principal cause of the incidence and progression of microvascular complications such as retinopathy, nephropathy, and neuropathy in people with diabetes (Taylor, 2003). The underlying pathophysiology of diabetes-related long-term complications largely arises from the effects of chronic hyperglycaemia, tissue glycosylation, changes in collagen metabolism and oxidative stress (Nishimura, Soga, Iwamoto, Kudo, & Murayama, 2005). Chronic complications are the major cause of diabetic morbidity. The complications of diabetes are far less common and less severe in people who have well-controlled blood sugar levels (Nathan et al., 2005). In 2012 diabetes was the direct cause of 1.5 million deaths

(WHO, 2014). At time of diagnosis, around 50% of people with T2D have a complication related to diabetes, and cardiovascular disease accounts for 50% of premature mortality seen in people with T2D (Spijkerman et al., 2003). Diabetes is predicted to become the 7th leading cause of death in the world by the year 2030. Total deaths from diabetes are projected to rise by more than 50% in the next 10 years (WHO, 2014).

Diabetic Neuropathy is a common complication of T1D and T2D. It is characterised by injury or dysfunction of nerve fibres usually in the feet (Javed, Alam, & Malik, 2015). It causes clinical manifestations and disabilities of diverse spectrum and considerable severity. Both peripheral nerves (sensory and motor) and the autonomic nervous system can be affected. Often due to a combination of sensory neuropathy and vascular damage, there is an increased rate of skin ulcers and infection and, in serious cases, necrosis and gangrene. Diabetic neuropathy can have a significant and negative impact on quality of life, impair physical and psychological functioning and lead to anxiety and sleep disturbances (Javed et al., 2015). Diabetic foot is the reason why those with diabetes are prone to leg and foot infections and why it takes longer for them to heal from leg and foot wounds and is the most common cause of non-traumatic adult amputation, usually of toes and, or feet, in the developed world (Veves, Backonja, & Malik, 2008).

Diabetic nephropathy is damage to the kidneys which can lead to chronic renal failure, eventually requiring dialysis (Harris, 1995). Diabetic nephropathy is the most common cause of end stage renal disease in most of the countries worldwide (Sharaf El Din, Salem, & Abdulazim, 2017). It increases the overall 10-year mortality among diabetic patients at least 6 folds compared to healthy age matched non-diabetic individuals (Afkarian et al., 2013).

Diabetic retinopathy is the leading cause of visual disability. Diabetes remains the most common cause of blindness in the working age group of the Western world (Chatterjee & Davies, 2015). Significant retinopathy is rarely encountered in the first five years of insulin-dependent diabetes mellitus, however, over the subsequent two decades, the vast majority of people with diabetes develop retinal changes. The establishment of national retinal screening programmes in the UK has improved the detection and early referral to ophthalmology services of patients with diabetic retinopathy (Gupta et al., 2013). Panretinal photocoagulation and newer therapies such as injectable inhibitors of vascular endothelial growth factor can prevent worsening of proliferative retinopathy and onset of visual

impairment (Marozas & Fort, 2014). In individuals with T2D, up to 20% may be found to have retinopathy at the time of first diagnosis of diabetes and most develop some degree of retinopathy over subsequent decades (Gupta et al., 2013).

Cardiovascular diseases (CVD; coronary heart disease and strokes) are the leading causes of death in the diabetic population, responsible for between 50% and 80% of deaths in people with diabetes (Ding, Sun, & Shan, 2017). In contrast to people with no diabetes, heart disease appears earlier in life, affects women almost as often as men, and is more often fatal in people with diabetes. Around 50% of deaths of people with diabetes are due to ischemic heart disease (Harris, 1995). Diabetes has become one of the major causes of premature illness and death in most countries, mainly through the increased risk of CVD (WHO, 2014).

A recent case report by King and colleagues reported a further complication of diabetes. Liver disease in those with diabetes is common and is frequently the result of hepatic steatosis; an accumulation of fat in the liver. Diabetic hepatosclerosis is a relatively recent microvascular complication observed in liver biopsies of people with diabetes presenting with cholestasis (King et al., 2016). However, its effect on morbidity and mortality is not yet known.

Diabetes and Oral Health

The complications described above are well known, but the awareness of oral health-related complications is less common. However, diabetes is a significant risk factor for serious, progressive periodontal disease (Southerland, Taylor, & Offenbacher, 2005). Likewise, periodontal disease may contribute to the progression of impaired glucose tolerance in diabetes (Loe, 1993; Pontes Andersen, Flyvbjerg, Buschard, & Holmstrup, 2007). Loe (1993) for example, described periodontal disease as 'the sixth complication' of diabetes. It has also been described as a complication of diabetes that is often overlooked as it is not often included in the management of diabetes, education programmes or in the screening of complications (Dunning, 2009).

Periodontal disease

Periodontal diseases are collectively a very common group of oral diseases. Periodontal disease is predominantly caused by plaque-induced inflammatory lesions and includes gingivitis, in which the inflammation is confined to the gingiva, and is reversible with good

oral hygiene, and periodontitis, in which the inflammation extends and results in tissue destruction and alveolar bone resorption (Chauhan & Haslam, 2012). Tissue destruction in periodontitis causes breakdown of the collagen fibres of the periodontal ligament, resulting in the formation of a periodontal pocket between the gingiva and the tooth (Preshaw et al., 2012). Periodontitis is a slow progressing disease but the tissue destruction that occurs tends to be irreversible. In the early stages, the condition is typically asymptomatic; it is not usually painful, and many patients are unaware of its presence until the condition has progressed enough that the teeth have become mobile. The pockets deepen as a result of the further damage of fibres of the periodontal ligament and the resorption of the alveolar bone that occurs alongside the progressing attachment loss. Advanced periodontitis is characterised by gingival erythema and oedema, gingival bleeding, gingival recession, tooth mobility, drifting of teeth, suppuration from periodontal pockets, and tooth loss (Preshaw et al., 2012).

Prevalence of periodontal disease

The condition is very common; periodontal diseases are prevalent both in developed and developing countries and affect about 20-50% of the global population (Nazir, 2017). Periodontitis is therefore a highly prevalent, but largely hidden, chronic inflammatory disease. Furthermore, it has negative and profound impacts on many aspects of an individuals' daily living and quality of life, affecting confidence, social interactions and even food choices (O'Dowd, Durham, McCracken, & Preshaw, 2010).

The negative impact of periodontal disease on oral health related quality of life (OHRQoL) has been investigated less than other oral problems, such as dental caries and tooth loss. A better understanding regarding the impact of periodontal disease can help ensure planning and treatment meets the needs and concerns of the patient. A recently performed systematic review of the literature aimed to find consistent evidence regarding the negative impact of periodontal disease on OHRQoL among adolescents, adults and older adults (Ferreira, Dias-Pereira, Branco-de-Almeida, Martins, & Paiva, 2017). This review of thirty-four studies found that severe periodontitis had a significantly greater impact on OHRQoL than mild to moderate periodontitis. Gingivitis also exerted an impact, albeit less than periodontitis, and was associated with pain as well as difficulties involving tooth brushing and wearing dentures, demonstrating a negative correlation with comfort. Whilst the review had its limitations such as the inclusion of observational studies which generally have a greater risk of bias and confounding variables, which can compromise the internal and external validity

of the findings,, it did conclude that having greater knowledge regarding the impact of periodontal disease would allow periodontists to clarify to patients the importance of periodontal treatment to overcome this impact (Ferreira et al., 2017).

Periodontal disease and diabetes

Periodontitis is said to be the most common chronic inflammatory disease seen in humans, affecting nearly half of adults in the UK and 60% of those over 65 years (Chapple, 2014). Between 60% to 65% of the U.S. population has periodontal disease, and the prevalence increases to 85% to 90% in individuals with diabetes (Iacopino, 2001). The risk of periodontitis is also described as increasing by approximately threefold in diabetic individuals compared with non-diabetic individuals (Mealey & Ocampo, 2007). In the US National Health and Nutrition Examination Survey (NHANES) III, adults with poorer diabetes control had a significantly higher prevalence of severe periodontitis than those without diabetes after controlling for age, ethnicity, education, sex and smoking (Tsai, Hayes, & Taylor, 2002). The chronic effect of hyperglycaemia enhances the formation of biologically active glycosylated proteins and lipids, which endorse inflammation and increases the likelihood of periodontal infection (Lalla, Lamster, Drury, Fu, & Schmidt, 2000). In addition, lipopolysaccharide, a bacterial endotoxin, plays a role via the actions of Toll-like protein receptors, which stimulate the inflammatory response and the immediate immune response (Takeda & Akira, 2005). The immune response to infection is therefore altered in the presence of hyperglycaemia, so that white cell mobility and phagocytic capacity is reduced.

Once periodontal disease and diabetes occur together, a vicious cycle develops: diabetes predisposes the individual to periodontal disease, which in turn contributes to hyperglycaemia, which affects other tissues and organs, including the oral cavity. Preventing and/or effectively managing periodontal disease can reduce hyperglycaemia, subsequent insulin requirements, and overall HbA1c (Danesh, Collins, Appleby, & Peto, 1998). Periodontal infection is also associated with other long-term diabetes complications, such as atherosclerosis (Nichols, Fischer, Deliargyris, & Baldwin, 2001) and nephropathy (Choudhury & Luna-Salazar, 2008).

Diabetes is one of several systemic diseases that contributes to periodontal disease in the oral cavity by exaggerating the host response to the local microbial factors, for example

endotoxin, resulting in destructive periodontal breakdown (Ryan, Carnu, & Kamer, 2003). Metabolic control is important in people with diabetes because they are more susceptible to infections than those without diabetes (Hayes, Leal, Gray, Holman, & Clarke, 2013).

Periodontal infection may adversely affect glycaemic control. In a systematic review, Taylor (2003) reviewed the evidence of how the treatment of periodontal disease can positively affect glycaemic control. Although results were limited in terms of quantity, breadth and strength of evidence, there was still support for the notion that treating periodontal infections with adjuvant antibiotics could have a beneficial effect on glycaemic control, such as, improved HbA1c values, in both T1D and T2D. They concluded that it is important for health professionals to incorporate a thorough oral examination and necessary periodontal care, in terms of prevention and treatment in management regimes for people with diabetes. Older studies have shown that scaling and root planing with systemic doxycycline therapy is associated with an improvement in periodontal health as well as a significant improvement in glycaemic control, as measured by HbA1c (Grossi et al., 1997; Grossi et al., 1996). To this finding, Ronningen and colleagues, in a review of diabetes and oral health added that periodontal therapy should primarily consist of a systematic treatment by mechanical debridement without the use of antibiotics (Ronningen & Enersen, 2012). They also concluded that the goal of therapy for oral manifestations is to promote oral health in those already diagnosed with diabetes, to help prevent and diagnose diabetes in undiagnosed dental patients receiving routine stomatological care and to enhance the quality of life for patients with this incurable disease. In cases where the response to the conventional treatment is inferior, the use of antibiotics as a supplement should always be based on a microbial diagnosis and susceptibility testing of the microbiota. Thus, by reducing the inflammation after periodontal therapy, insulin sensitivity may be restored, therefore improve glycaemic control (Mealey & Rose, 2008).

One of the most recent Cochrane systematic reviews published in the area of periodontal disease and diabetes looked into the suggestion that a bidirectional relationship exists between glycaemic control and periodontal disease. Therefore, the objective of this Cochrane review was to investigate the effect of periodontal therapy on glycaemic control in people with diabetes (Simpson et al., 2015). RCTs were found whereby participants had diabetes and a diagnosis of periodontitis, and where interventions involved periodontal treatment. Outcome data was collected on blood glucose levels measured by HbA1c. Of the thirty-five

studies found, the authors concluded that there was low quality evidence that the treatment of periodontal disease actually improved glycaemic control in people with diabetes, with a mean percentage reduction in HbA1c of 0.29% at 3-4 months. There was insufficient evidence to demonstrate that this was maintained after four months. There was no evidence to support that one periodontal therapy was more effective than another in improving glycaemic control. It would thus appear that ongoing professional periodontal treatment is required to maintain clinical improvements beyond 6 months.

As well as periodontal diseases such as gingivitis and periodontitis which are modifiers of glycaemic control, there are several other oral manifestations of diabetes including, burning mouth syndrome, candidiasis, dental caries and salivary dysfunction (Ronningen & Enersen, 2012; Ship, 2003).

Financial cost of diabetes

Management of diabetes is expensive and set to get costlier. Managing the condition and its devastating complications imposes a huge societal and economic toll on healthcare systems worldwide (Chowdhury & Bennett-Richards, 2013). Diabetes UK report that 10% (around £11 billion) of the UK healthcare expenditure is on management of diabetes and its attendant complications, although the actual cost may be double this figure if indirect costs are included (Diabetes UK, 2012). However, it has been reported that annual costs of diabetes to the NHS are estimated at £23.7bn and projected to rise to £39.8bn by 2035 (Hex et al., 2012). In a recent study, the cost of severe hypo-glycaemia in patients with T2D in England was calculated, and the authors reported that hospitalisation as a result of severe hypoglycaemic events was associated with considerable financial costs to the NHS (Holbrook et al., 2017).

Preventing diabetes-related complications

The development of diabetic complications is strictly related to metabolic control (Wang, Lau, & Chalmers, 1993). Nicolucci and colleagues found several factors related to the development of major diabetic complications when they compared 886 patients with long-term diabetic complications and 1,888 control participants without complications (Nicolucci et al., 1996). Among patient characteristics, male sex and age for patients between 50 and 69 years of age as opposed to those younger than 50 years of age were associated with an increased risk of diabetes-related complications. The type and duration of diabetes were the

most important clinical predictors of diabetic complications. They also found that the presence of hypertension was associated with the development of diabetic complications, particularly when it was poorly controlled by treatment. Patients who needed help to reach a health care facility and those who did not regularly attend such a facility were at higher risk of developing complications, educational aspects were also related to the outcome: patients who did not receive any kind of educational intervention had an increased risk of developing complications, while self-management of insulin therapy had a protective effect. It was summarised that by removing avoidable risk factors, the number of diabetic complications considered could be reduced by more than one-third (Nicolucci et al., 1996).

To date, the most successful strategy for preventing complications of diabetes is intensive treatment of hyperglycaemia. The DCCT demonstrated the value of this approach with a curvilinear relationship between glycosylated haemoglobin and the incidence of retinopathy, thus demonstrating that the incidence of retinopathy, nephropathy, and neuropathy could be reduced by intensive treatment (Clark & Lee, 1995; Colwell, 1994). A similar trial was conducted in the UK; The UK Prospective Diabetes Study (UKPDS) was a randomised, multicentre trial of glycaemic therapies in 5,102 patients with newly diagnosed T2D, running for twenty years in 23 UK clinical sites and showed conclusively that the complications of T2D previously often regarded as inevitable, could be reduced by improving blood glucose and/or blood pressure control (Stratton et al., 2000). Research such as this clearly demonstrates the need for early intervention in the form of treatment and tight glucose control, therefore screening for undiagnosed diabetes is one way to begin this process. On the basis of this work, the National Diabetes Prevention Programme (NDPP) was launched. It is an evidence-based lifestyle change program which has been demonstrated to delay or prevent the development of type 2 diabetes among people at high risk. NHS England, Public Health England (PHE) and Diabetes UK initiated a UK national diabetes prevention programme in 2015. The National Health Service Diabetes Prevention Programme (NDPP) commenced during 2016 with a first wave of 27 areas covering 26 million people, half of the population, making up to 20,000 places available for people to receive tailored, personalised help to reduce their risk of T2D including education on healthy eating and lifestyle, help to lose weight and bespoke physical exercise programmes (National Cardiovascular Intelligence Network, 2015).

Improved glucose control has been a treatment mainstay in the management of diabetes, and the number of pharmacological and non-pharmacological strategies to control glucose levels has increased substantially in the past decade (Zoungas et al., 2017). Despite the growing number of therapeutic options, there is uncertainty regarding the clinical benefits and risks of varying intensities of glucose control for patients with T2D (Hemmingsen et al., 2013). Intensive glucose control is understood to prevent complications in adults with T2D. Therefore a meta-analysis was conducted to estimate the effects of more intensive glucose control, compared with less intensive glucose control, on the risk of microvascular events; specifically kidney events, eye events and nerve events (Zoungas et al., 2017). Participant data was collected from RCTs with a total of more than 27,000 participants. Compared with less intensive glucose control, more intensive glucose control resulted in an absolute difference of -0.90% (95% CI -1.22 to -0.58) in mean HbA1c at completion of follow-up. The relative risk was reduced by 20% for kidney events, and by 13% for eye events. There was no reduction in nerve events. More intensive glucose control over 5 years reduced both kidney and eye events, and was important for the prevention of long-term microvascular complications in adults with T2D.

Screening for Diabetes

In view of the steady increase of life expectancy and the corresponding rise of chronic disease rates during the past decade, health promotion and primary and secondary preventive health services have become more and more important (Shippee et al., 2012). There is now an emphasis on services which aim to prevent disease and illness through disease surveillance, and surveillance for disability and other health problems, providing advice and counselling on good health maintenance and well-being through living a healthy lifestyle (DoH, 1989). This is often demonstrated in screening programmes that have been developed to comply with the idea of health checks and surveillance.

Screening is a process of identifying apparently healthy people who may be at increased risk of a disease or condition (Edwards et al., 2013). They can then be offered information, further tests and appropriate treatment to reduce their risk or any complications arising from the disease or condition (Waugh et al., 2013).

Screening is not the same as diagnosis: most screening programmes look for risk factors for a particular disease or condition. Some individuals with these risk factors will never develop the condition or disease, and some who develop the disease or condition will not be picked up by screening. When choosing who to screen and for which conditions, the benefits are weighed against the harms (Gilmer & O'Connor, 2010; UK National Screening Committee, 2014).

It is well-recognised that T2D has become a huge burden for the worldwide general adult population (UK National Screening Committee, 2008, 2014). The review by the National Screening Committee in 2014 found that interest in screening had been stimulated by a number of factors including the rising number of people with diabetes and with people with raised blood sugar who do not meet the formal level for a diagnosis of diabetes. The committee recognised that primary prevention measures (such as lifestyle change) were having a limited effect, increased understanding of how raised blood sugar (at any level) related to a broad range of vascular risk, change in international views on testing, improvement in management of diagnosed diabetes and developments in treatment of people with raised blood sugar but who were not diabetic. The review came to the conclusion that, on the balance of the evidence, universal screening was not recommended. However, the report suggested that this did not rule out the value of early detection in high risk groups or, in England, the NHS Health Check; a free check-up of your overall health which assesses whether a person is at higher risk of getting certain health problems, such as heart disease, diabetes, kidney disease and stroke.

Screening for T2D will potentially allow for early diagnosis and treatment. This is considered to be important as early diagnosis and treatment could prevent future associated microvascular and macrovascular complications. An estimated 50% of people with diabetes are currently undiagnosed (International Diabetes Federation, 2013). According to several major studies, around 20–30% of people with T2D have already developed complications at diagnosis (Marre & Travert, 2010). The approach could be either to screen for T2D alone, or to anticipate the progression to diabetes from pre-diabetic states and therefore work with a lower threshold to allow screening for both impaired glucose tolerance (IGT) and T2D. In addition, for earlier diagnosis of T2D, interventions could be designed for those identified with IGT in order to attempt to delay the onset of T2D and/or to prevent complications (Marre & Travert, 2010).

The diabetes screening debate

The World Health Organization defined the minimal criteria to propose a disease for an early detection programme (Wilson, Jungner, & WHO, 1968). The five main reasons for recommending a disease for a screening programme are:

1. The disease should represent an important health economic concern.
2. The natural history of the disease and the prognosis when not treated should be known.
3. There should be a latent preclinical time before the occurrence of symptomatic disease during which diagnosis is possible.
4. There should exist reliable and safe diagnostic tests which are acceptable for screening the population.
5. The disease should be able to be efficiently treated when diagnosed; the earlier the treatment is started the more efficient it is.

With respect to these early detection criteria, there is plethora of opinion suggesting as to why diabetes is a condition that should be screened for. The following section outlines some arguments for and against screening for diabetes.

T2D is typically a disease characterised by a latent phase before the occurrence of the clinical symptoms. This has been demonstrated by various epidemiological surveys and during detection programmes. Moreover, at the time of clinical diagnosis, often due to the symptoms of hyperglycaemia, a percentage of these newly diagnosed diabetic patients already have complications, especially retinopathy (2–39%), nephropathy (8–18%) or neuropathy (5–13%). From this, research has now estimated that the preclinical phase can last from 7 to 12 years (Engelgau et al., 2000). This means there a severe delay in diagnosis and treatment. During this preclinical stage, there is a possibility of making an earlier diagnosis since hyperglycaemia may remain asymptomatic for years. Performing a blood glucose assessment is relatively easy and acceptable to individuals being screened (Friman, Hultin, Nilsson, & Wardh, 2015). A frequent question when considering the need to screen for T2D is, does a treatment started at the phase of screening result in better outcomes? The evidence is said to be weak and there is not much research to demonstrate that screening for diabetes provides a true advantage in terms of preventing complications (WHO, 2003).

The rest of this section outlines chronologically, the arguments that have been put forward for and against screening for diabetes. Formal screening dates back to the 1940s, where the findings of a population study in Massachusetts showed that for every known diabetic case, there was another person with undiagnosed diabetes (Wilkerson & Krall, 1953). From this, large-scale screening detection programmes emerged and the current urine tests were replaced by blood-based methods. The American Diabetes Association subsequently endorsed blood glucose screening programmes, and local diabetes organisations facilitated these programmes. Although the screening programmes uncovered plenty of new cases of diabetes, negative aspects of the programmes also emerged. They were inadequately organised, and cases of chronic hyperglycaemia often would go unrecognised or 'lost' in the system. Referrals were delayed evoking criticism from patients and professionals. The cost of regular evaluations, the side effects of inappropriately using oral hypoglycaemic agents and issues related to employability and insurability added to the negative view of the usefulness of diabetes screening programmes, and led to the medicine and federal agencies to re-evaluate the worth of these programmes. As a consequence, in 1979 Herron noted that glucose intolerance should not be screened for in non-pregnant populations (Herron, 1979). Although his report did not escape criticism, it reflected a change in the number of screening programmes and impacted on diabetes organisation across the world.

According to O'Sullivan and Kannel (1983), proper evaluation of the worth of screening for diabetes depends partly on the stage of diabetes to be detected. Not many have questioned the worth of screening for and detecting the obvious stage of diabetes, where it is well developed and characterised by chronic hyperglycaemia, as there is obvious value in preventing the acute complications of diabetes. However, the detection of asymptomatic hyperglycaemia poses a number of difficult problems. In order to improve upon the problems created in past screening programs, O'Sullivan and Kannel (1983) suggested defining hyperglycaemia less equivocally, and in addition, the management of the individual and the programme as a whole should be in terms of risk evaluation. They also suggested using the term "impaired glucose tolerance" (IGT) rather than diabetes to lessen the extent of anxiety and other adverse social and psychological aspects created in earlier screening programmes. The health benefits for the individual is fundamental to questioning the worth of such a programme, therefore, O'Sullivan and Kannel (1983) suggested that possible benefit of screening for diabetes could

best be accrued from focussing on a subset of the population, those most vulnerable to developing diabetes. Screening programmes would be worthwhile for the individuals who are obese, those with a family history of diabetes, those at risk for cardiovascular disease and pregnant individuals. They were of the opinion that screening the general population should be carried out with caution and should only be done if the activity is part of a diabetes or cardiovascular disease health education or prevention programme, and if the term diabetes is used cautiously by requiring blood glucose screening levels to be obviously high. Finally, they made a suggestion, that lowering the blood glucose levels for screening in the future should be considered if there is to be a shift from just detecting diabetes to preventing the development of diabetes.

In 1997, the American Diabetes Association proposed the screening of all patients aged over 45 years by measuring fasting blood glucose every three years, in addition to screening patients from high-risk ethnic groups, and younger patients with hypertension, obesity, a family history of diabetes in a first degree relative, or a family history of gestational diabetes (Mellitus, 1997). Such a policy has major resource implications for the NHS, and so the debate on whether to screen for diabetes in the UK continued (Wareham & Griffin, 2001).

Screening for diabetes has the potential to detect pre-diabetes, a condition in which a person's blood sugar levels are higher than normal, but not yet at a level to be classified as diabetes. Being diagnosed with pre-diabetes is important because having pre-diabetes and subsequently making the necessary lifestyle changes can greatly reduce the chances of the condition developing into diabetes. However, despite this information, other researchers have stated that there is insufficient evidence to recommend screening for diabetes and that we still need to know whether treating asymptomatic people with slightly raised glucose concentrations is effective (Stolk, 2007).

According to Engelgau, Narayan & Herman (2000), T2D fails to meet all of the criteria for suitability for screening. Lamont and colleagues undertook a study to explore the views of general practitioners (GPs) and practice nurses towards the benefits and barriers of screening for T2D (Lamont, Whitford, & Crosland, 2002). Semi-structured interviews were carried out with 10 GPs and nine practice nurses in eight general practices in the UK. Participants answered open-ended questions about benefits of screening for T2D, the impact of screening

on primary care, barriers to implementing screening and the consequences for patients of screening.

Despite the growing expression concerning the practice of evidence-based medicine (Niessen, Grijseels, & Rutten, 2000), only two GPs constructed their beliefs about the effectiveness of screening for T2D from a scientific evidence-based approach. They expressed uncertainty as to whether any real benefits would come from a screening programme and were more inclined to wait until there was clear evidence available. Their views did not include the trust generated by earlier detection, but were more likely to mention provoking anxiety in patients and the social impact of screening. However, there was a contrasting belief in that screening for T2D is worthwhile. This belief came from a complex interaction of factors including perceptions of patient desires, previous experience and evidence from other sources. A lack of resources in terms of time and finance were seen as the major barrier to implementing screening. Results also demonstrated a belief among primary care practitioners that patients exert little effort in gaining or maintaining lifestyle changes. Combined with reluctance among the GPs to place these patients on multiple medications, an issue was created as to whether screen-detected cases would benefit if they were not then subsequently intensively treated. The chances that the elderly and socially deprived, who may benefit most from screening and subsequent interventions, would be targeted was undermined by the doubt about the effectiveness of treatment in such sub-groups. Screening for T2D can be seen from this study as reinforcing a paternalistic medical model, whereby a "knowledgeable doer", in the "best interests" of the patient, subjects the patient to a test with little consent but possible major consequences. A major motivator towards the introduction of screening in this study appeared to be the perception that screening was reflecting the desire of patients for earlier detection of disease (Lamont et al., 2002). In conclusion, the authors stated that the belief that screening for T2D is worthwhile was based not on evidence for the effectiveness of such a screening programme, but rather on an intricate interaction of factors including perceptions of patient desires, previous experience, and evidence from other sources (Lamont et al., 2002).

Later on, Gilmer and O'Connor (2010) discussed the growing importance of diabetes screening following recent trials which quantified the risks of intensive glycaemic control such as, high treatment costs, weight gain, increased risk of severe hypoglycaemia and even an increased risk of death (Gilmer & O'Connor, 2010). They pointed out that more attention

is needed on primary prevention of T2D and the identification of cases of diabetes and its dangerous progenitor pre-diabetes. Those then identified with pre-diabetes may benefit from lifestyle or pharmacological intervention that could potentially prevent or delay the onset of diabetes.

At around the same time, Chatterjee and colleagues investigated the economic justification for screening for pre-diabetes and diabetes and reported that population-based screening for diabetes may be cost saving (Chatterjee, Narayan, Lipscomb, & Phillips, 2010). The economic costs of hyperglycaemia are substantial. Early detection of the disease can allow management to prevent or delay the development of diabetes and diabetes-related complications. Participants aged 40-74 years without a previous diagnosis of diabetes were recruited for diabetes screening. The projected health system and societal costs over 3 years for 1,259 adults were calculated, comparing costs associated with five opportunistic screening tests. They concluded that screening can be cost-saving compared to no screening from a health system perspective, but not necessarily from a societal perspective.

It is now established that microvascular and macrovascular complications are sometimes present at diagnosis, even in prediabetes following an impaired fasting glucose or impaired glucose tolerance (Diabetes Prevention Program Research Group et al., 2007; Nguyen, Wang, & Wong, 2007). As many as 25% of people with a new diagnosis of diabetes already have established diabetic retinopathy or microalbuminuria, which has been interpreted to mean that there is on average a 7-year gap between the actual onset and the diagnosis of T2D (Harris, 1993; Thompson et al., 1996). To this end, the reality remains that there is a crucial need to identify diabetes and its precursors earlier and more efficiently, and therefore screening for diabetes is crucial.

To conclude, at present, a systematic national screening program for diabetes is not recommended in the UK; however, the National Screening Committee does recommend selective screening as part of overall vascular risk assessment (Waugh et al., 2013). Accordingly, the current NICE guidelines advise health practitioners to carry-out a two-stage strategy, involving the use of screening questionnaires in stage one, followed by a blood test at stage two if necessary (Guess, Caengprasath, Dornhorst, & Frost, 2015). For people at low risk of diabetes, the guidance recommends a short consultation to advise the patient of their current low risk status and to offer brief risk reduction advice. For people with a high risk

score, but normal blood glucose control, a discussion of the patient's particular risk factors is recommended, alongside lifestyle advice to address modifiable risk factors. People with a high-risk score should be offered a referral to a local, evidence-based intensive lifestyle-change programme (NICE, 2012).

Screening tests for Diabetes

There is no global consensus on the screening strategy and test for detection of diabetes (Zhang, Hu, Zhang, Mayo, & Chen, 2015). Ideally, a screening test should be both sensitive (have a high probability of being positive when the subject truly has the disease) and specific (have a high probability of being negative when the subject does not have the disease) (Maxim, Niebo, & Utell, 2014). However, increasing sensitivity reduces specificity, and increasing specificity reduces sensitivity. Screening tests should also be reliable and reproducible (Engelgau et al., 2000).

A systematic review by Bennett, and colleagues in 2007 did not find clear evidence to suggest that one test, HbA1c or FPG, was superior to the other in screening for diabetes or IGT (Bennett, Guo, & Dharmage, 2007). HbA1c and FPG were found to be equally effective screening tools for the detection of T2D. On the whole, HbA1c had slightly lower sensitivity but higher specificity than the FPG in detecting diabetes, but neither was effective in detecting IGT though neither FPG nor HbA1c involve a glucose challenge, so they are unlikely to detect IGT.

The measurement of HbA1c provides an assessment of long-term (around 3 months) glycaemic control and is regularly used in diabetes management. The WHO in their 2006 report did not recommend using HbA1c for the diagnosis of T2D because HbA1c measurement was not widely available in many countries throughout the world, global consistency in its measurement was problematic, and also because the HbA1c result was said to be influenced by several factors including anaemia and abnormalities of haemoglobin. More recently however, it was recommended by the ADA and the International Expert Committee (IEC) for use in the diagnosis of diabetes (Bloomgarden, 2009).

Conversely, it was recommended that A1C not be used as a *primary* diagnostic test; instead, it has been argued that it should be considered an optional diagnostic tool or used as a screening test that may suggest the need for additional glucose measurements (American Association of Clinical Endocrinologists Board of Directors & American College of Endocrinologists Board of Trustees, 2010). HbA1c level is not affected by short-term lifestyle changes, whereas a few days or weeks of dieting or increased exercise prior to screening can significantly affect FPG and OGTT, therefore, HbA1c probably accurately reflects longer-term glycaemia (Tahara & Shima, 1993). In a review of diagnostic tests, it was recommended that this long-established and universally accepted measure of chronic glycaemia, should be used to screen and diagnose diabetes (Saudek et al., 2008).

Fasting plasma glucose (FPG) has been a commonly used tool in screening diabetes, but it has a large random variation, it only reflects current glycaemic status, and requires people to fast for at least 8 hours before the test. Oral glucose tolerance test (OGTT) has been shown to be the most valid tool for diagnosing diabetes (Schwarz et al., 2009). However, OGTT is more expensive, inconvenient, and has weak reproducibility, making it practically unacceptable for most patients and providers as the first line of screening tool (Waugh et al., 2007). Glycosylated haemoglobin reflects long-term glycaemic control and is a more accurate and stable measure than FPG levels (Goldstein et al., 2004). In 2010, the International Expert Committee recommended the use of HbA1C, a non-fasting test, to diagnose diabetes (ADA, 2010). The recommendations imply that the practical advantages of HbA1c over FPG and OGTT will make diabetes screening more widespread. However, the sensitivity of using HbA1c alone in detecting diabetes is unacceptably low, ranged from 63.2% at a cut-off value of 6.1% to 28.3% at a cut-off value of 7.0% in different populations (Buell, Kermah, & Davidson, 2007).

Multivariate risk scores have been developed in recent years to predict diabetes risk for healthy individuals (Buijsse, Simmons, Griffin, & Schulze, 2011). Simple, practical, non-invasive and inexpensive methods are needed to identify individuals at high risk for diabetes and to limit the proportion of the population requiring diagnostic glucose tolerance tests (Alberti, Zimmet, & Shaw, 2007). The use of FPG levels as a population-level screening tool is not recommended due to the variability of its plasma levels and its low cost-effectiveness (Waugh et al., 2007). However, the cost-effectiveness improves when used in high-risk subgroups (i.e. age over 45 years, history of gestational diabetes, family history of diabetes or

obesity). Salinero-Fort and colleagues reported that there was no consensus on the selection of the optimal high-risk subgroups or on how regularly these screens should be performed (Salinero-Fort et al., 2015). As a consequence, risk scores have been developed in order to better identify high risk participants. The IDF recommends the use of brief patient questionnaires to help healthcare professionals to quickly identify people who may be at a higher risk and who need to have their level of risk further investigated. This type of questionnaire could also be used by individuals for self-assessment. Using a diabetes risk score questionnaires for screening undiagnosed and/or pre-diabetes have been developed and validated in different populations worldwide (Zhang, Wang, et al., 2015). Some diabetes risk scores are based on demographic, clinical information and modifiable lifestyle factors such as diet and physical activity, and do not require blood draws and laboratory tests. Therefore, they are cheap and easy to be applied in the primary care setting and in large scope screening programs. Although collecting data from a questionnaire is likely less costly and more acceptable than methods of screening involving more invasive measures such as blood glucose testing, difficulties in distributing questionnaires, the time required to complete them, the complexity of computing the results, issues related to reporting bias, and unavailability of some required information may hamper their population-wide application. Questionnaires may also create anxiety or false reassurance (Buijsse et al., 2011). The most well-known scores are those developed by the ADA (Bang, Edwards, Bombardier, & et al., 2009), the German Institute of Human Nutrition (Schulze et al., 2007), and the Finnish Diabetes Association (FINDRISC) (Lindstrom et al., 2003). They all have certain common advantages: the variables are simple to collect; they have open access via websites; they are inexpensive and quick, and can be self-administered. All have a similar diagnostic accuracy, with equivalent AUC for ROC, compared with those that add laboratory variables (Aekplakorn et al., 2006; Schmidt et al., 2005).

Noble and colleagues discussed the properties of seven validated diabetes risk scores which they judged to be most promising for use in clinical or public health practice (Noble, Mathur, Dent, Meads, & Greenhalgh, 2011). These included for example, the Cambridge Risk Score (Rahman, Simmons, Harding, Wareham, & Griffin, 2008), Ausdrisk (L. Chen et al., 2010), QDScore (Hippisley-Cox, Coupland, Robson, Sheikh, & Brindle, 2009), FINDRISC (Lindstrom et al., 2003; Stern, Williams, & Haffner, 2002), and San Antonio Risk Score (Stern et al. 2002). The seven risk scores were classified as having high potential for use in

practice, offered broadly similar components and had similar discriminatory properties (area under receiver operating characteristic curve varied from 0.74 to 0.85).

Despite their widespread use, few studies have directly compared the performance of the different scores. However, in one particular cross-sectional study of 2759 Taiwanese participants, Lin and colleagues evaluated the performance of different risk scores for detecting T2D, metabolic syndrome and chronic kidney disease. Their data showed the FINDRISC to be one of the more superior scores for identifying the risk of undiagnosed diabetes (Lin et al., 2009).

What are the psychological predictors of screening participation?

Understanding the principle determinants in preventive health practices such as screening attendance, is of major importance in order to optimise any kind of preventive health strategy (Brunner-Ziegler et al., 2013). If attendance rates at such screening programmes are to be increased it is imperative that the factors which may lead to non-attendance be identified and managed (Norman & Connor, 1993).

Following several decades of research, a number of models of health behaviour have been designed in an attempt to map out the mediators of sociodemographic variables and identify proximal determinants of health behaviour. They provide a clear theoretical background to research, guiding the selection of variables to measure, the procedure for developing reliable and valid measures, and how these variables are combined in order to predict health behaviours and outcomes. Additionally, to the extent which they identify the variables important in predicting health behaviours and outcomes, they further our understanding of health (Abraham, Sheeran, & Henderson, 2011).

Motivational models unsurprisingly focus on the motivational factors such as protection motivation or threat that may underpin individuals' decisions to perform or not to perform certain health behaviours. Research associated with motivational models employs measures of intention as the dependent variable of interest suggesting that motivation is adequate for the action of successful behaviour. Models designed to account for the relatively poor correspondence between motivational variables such as intentions, and subsequent behaviour were then designed; this second group of social cognition models focus on connecting

motivation and behaviour. They focus on action control strategies that are designed to ensure that motivation leads to action. Then, at the most complex level, there are multi-stage theories that describe processes which both facilitate the action of behaviour and offer strategies for maintenance of a particular behaviour, such as screening attendance (Armitage & Conner, 2000; Power et al., 2008; St Quinton & Brunton, 2017).

Social cognition models may be employed to identify those variables which are important in reaching a decision to follow a health-related action in general, and to attend a health check in particular (St Quinton & Brunton, 2017). Understanding the factors that promote attendance in screening is important for the development of health promotion interventions aimed at improving the effectiveness of screening programmes.

In relation to breast cancer screening for example, results show that women who receive regular mammograms feel more personally susceptible to the disease than women who do not receive regular mammograms (Halabi et al., 2000; Lagerlund, Hedin, Sparen, Thurfjell, & Lambe, 2000). This supports the notion that screening for a particular disease can lead to negative psychological consequences. Other cognitive variables found to be associated with having had repeated mammograms include, perceived barriers or costs (Lagerlund et al., 2000; Lerman, Rimer, Trock, Balshem, & Engstrom, 1990; Taylor, Taplin, Urban, White, & Peacock, 1995); perceived benefits or effectiveness of mammograms (Lagerlund et al., 2000; Marshall, 1994); and perceived ease of screening re-attendance (Marshall, 1994). In a study following this, Drossaert and colleagues utilised the Theory of Planned Behaviour (TPB; (Ajzen, 1991)) as a theoretical framework to predict repeat attendance and patterns of attendance in breast cancer screening (Drossaert, Boer, & Seydel, 2002). A group of 2657 women completed a baseline questionnaire, approximately 8 weeks after receiving an invitation for an initial screening in the Dutch Breast Cancer Screening Programme. Data on actual attendance in second and third screening round were subsequently collected. Personal variables such as a family history of breast cancer, breast cancer in someone close and a fear of breast cancer were not related to repeat attendance. However, the TPB variables could explain approximately 17% of the variance in attendance in the second and third attendance rounds. Maintenance behaviour as measured by consistent attendance vs. dropout, was related to the TPB variables, but the amount of variance explained was only 6%. Initiation of behaviour as measured by consistent refusal vs. delayed attendance, was also related to TPB variables, with a considerably higher amount of explained variance than with the

maintenance behaviour. These results signify that the TPB variables are more related to the initiation of screening behaviour than to the maintenance of screening behaviour.

In a similar study looking to identify predictors of uptake into a screening programme, Bish, Sutton and Golombok (2000) looked at psychological predictors of uptake of women to a cervical screening programme. Among 142 women in London, the Health Belief Model (HBM; (Becker, 1974) and the TPB (Ajzen, 1991) were assessed in addition to the anticipated effect following non-attendance for screening. Results showed that a positive attitude towards having a smear test was the best predictor of an intention to be screened, being considerably more influential than a perception of a threat to health or perceived social pressure (Bish, Sutton, & Golombok, 2000). However, the TPB emerged as the superior model for predicting screening intentions, explaining 51% of the variance in comparison with only 4% explained by the HBM variables. Conversely, neither model was able to predict a significant amount of variance in uptake of screening three months later.

It is now known that patient acceptability of a screening programme will affect uptake (Webb et al., 2011), therefore it is crucial to ascertain patients' views as to why or not they participate. Eborall, Stone, Aujla, Taub, Davies and Khunti (2012) highlighted the barriers to uptake of the oral glucose tolerance test as a screening method, by qualitatively exploring the perspectives of those invited to attend the MY-WAIST screening study for type 2 diabetes, particularly the explanations for attending or not attending. Screening involved taking a self-measured waist circumference and completing a questionnaire to identify a risk-score, followed by a subsequent oral glucose tolerance test. Semi-structured interviews were conducted with 24 individuals aged 40-69 years, comprising 13 who attended and 11 who did not attend the screening. Reply slips from 73 individuals who declined the offer of screening were also analysed.

The researchers found two categories of influence on the decision about attending screening to emerge. The first was beliefs about T2D candidacy. T2D was more common among those who had attended, and lack of perceived severity of T2D was more common among those who did not attend (Eborall et al., 2012). The second was practical aspects about the screening strategy, in terms of the lengthy, early morning screening appointments, which were identified as a barrier to screening uptake. Conversely, those who attended for screening found the procedure largely acceptable. There was a tendency to consider T2D as lacking in

severity, and the idea that T2D is easily controllable was evident, particularly in non-attendees (Eborall et al., 2012). This study highlighted the barriers to diabetes screening attendance, demonstrating that beliefs about susceptibility to, and severity of, the condition affect whether people attend for screening, lending further support to how well social cognition model components can predict screening behaviour.

The psychological impact of screening

As with any screening programme the overall benefits should outweigh any physical and psychological harm associated with the programme (Eborall, Davies, Kinmonth, Griffin, & Lawton, 2007). It is important to identify possible adverse psychological effects of screening, and the resulting diagnosis and treatment in order to be able to deliver a successful screening programme with high levels of participation. It is therefore important to consider that a small adverse effect for the majority of participants who screen negative may outweigh a large benefit to the few diagnosed as having the condition, thus an assessment of the potential harms among all those invited to participate in screening is warranted.

An early systematic review of prospective studies of the psychological harms that can arise from screening across various conditions found that anxiety was often raised, at least in the short term, when a positive result is received, although it was unlikely to be raised by receiving a negative result (Shaw, Abrams, & Marteau, 1999).

More recently, Bond and colleagues carried out a systematic review in 2013 looking at the psychological effects on women receiving a false-positive mammography screening result. Eleven studies concluded that this disease-specific screening result consequently led to a negative psychological impact which had the potential to last for up to three years. However, this review only looked at screening results specific to breast cancer screening and to a false positive result (Bond et al., 2013). Therefore, due to the prolonged uncertainty throughout the screening process (French, Maissi, & Marteau, 2004), multistage screening programmes, such as those adopted in diagnosing diabetes were said to have the potential to cause increased distress. In 2015, Bond and colleagues interviewed twenty-one women, who had experienced false-positive screening mammograms to assess its psychological consequences. They concluded that whilst mammography screening-related anxiety could last for up to 12 years, breast cancer screening produced what they described as a ‘crisis of visibility’ whereby

accepting the screening invitation is taking a risk that you may experience unnecessary stress, uncertainty, fear, anxiety, and physical pain, but not accepting the invitation is taking a risk that malignant disease will remain invisible (Bond, Garside, & Hyde, 2015).

There is a continued uncertainty for example, concerning the feasibility, uptake and overall benefits and costs of screening for diabetes (Goyder, Wild, Fischbacher, Carlisle, & Peters, 2008). Screening for diabetes may affect physical and psychological morbidity and behavioural outcomes at the population level (Bankhead et al., 2003). Although screening programmes are often assessed on participation and attendance (Waugh et al., 2007), previous studies suggest that the method of screening for diabetes may influence uptake into the screening programme, with more invasive methods such as blood tests often being associated with lower attendance compared with non-invasive methods of screening such as the use of questionnaires (Engelgau et al., 2000; Lawrence, Bennett, Young, & Robinson, 2001). By using non-invasive procedures, such as looking at routinely available data to stratify a population according to diabetes risk and screening only those at highest risk for further assessment could potentially reduce the economic costs and possible psychological harms associated with some screening tests (Shaw et al., 1999). Patient characteristics have also been shown to influence attendance (Jepson et al., 2000), therefore by identifying factors that can influence uptake at these levels the facilitation of more appropriate organization and targeting of screening programmes can commence.

However, Adriaanse and colleagues concluded in a review of the impact of such screening programmes, that screening for T2D in the general population has no serious psychological side effects (Adriaanse & Snoek, 2006). In order to quantify these effects further, Eborall, Griffin, Prevost, Kinmonth, French and Sutton (2007) assessed both the short and long-term psychological effects of screening in a large cohort of people at high-risk of developing T2D. Further, they assessed the psychological impact of being invited to attend for screening at a general practice and of experiencing the screening tests and obtaining the results (Eborall et al., 2007). A total of 7380 adults, aged 40-69, in the top fourth for risk of having undiagnosed T2D (6416 invited for screening, 964 controls) were invited for T2D screening or not invited (controls). Those who attended completed questionnaires after a random blood glucose test and at 3-6 months and 12-15 months later. Controls were also sent questionnaires at the same time points. Those who did not attend for screening were sent questionnaires at 3-6 months and 12-15 months.

Results showed that there were no significant differences between the screening and control participants at any of the time points on any of the outcomes for anxiety, depression, diabetes-specific worry, or self-rated health. After the initial test, compared with participants who screened negative, those who screened positive reported significantly poorer general health, higher state anxiety, higher depression and higher diabetes-specific worry, although effect sizes were small. This implies that being required to return for further tests after an initial positive test result may have a small negative psychological impact.

Those screening negative at the initial test self-reported the best health and those with a diagnosis of diabetes self-reported the poorest health, however, this trend was no longer evident at 12-15 months, thus showing that the impact is unlikely to be of clinical, or long-term significance. The more screening tests that participants had before screening negative, the higher their worry scores were at 3-6 months about developing T2D, and this trend was maintained at 12-15 months.

The findings confirmed the position that screening for T2D does not create psychological costs (Adriaanse et al., 2004). On the basis of these findings, the authors commented that the implementation of a national diabetes screening programme based on the stepwise screening procedure used in their trial is unlikely to have significant consequences for patients' psychological health, therefore giving reason to support a potential screening programme for T2D. Again, more recently, the potential for harm from diabetes screening that is, anxiety, depression, and a decreased quality of life, are reported to appear to be minimal regardless of the diagnosis (Paddison et al., 2011).

Where can diabetes screening take place?

Exploring key opportunities to detect disease and carry out screening programmes through providing alternative locations as a setting for screening, means we may widen access to those at risk who do not have access to healthcare or those who do not routinely access conventional healthcare settings (Howse, Jones, & Hungin, 2011b).

In 1997, The American Diabetes Association proposed the screening of all patients over 45 years of age, by measuring fasting blood glucose every three years, in addition to screening

patients from high-risk ethnic groups and younger patients with hypertension, obesity, a family history of diabetes in a first degree relative, or a family history of gestational diabetes (The Expert Committee On The Diagnosis And Classification Of Diabetes Mellitus, 1997). Lawrence, Bennett, Young and Robinson (2001) undertook a study to assess the feasibility of implementing the American Diabetes Association's policy in the UK, in a local general practice with a relatively low risk population. They also assessed the cardiovascular risk profile of patients diagnosed as having diabetes as a result of screening to see whether they were identifying a previously unrecognised high-risk population (Lawrence et al., 2001). A total of 2481 patients aged over 45 not known to have diabetes were invited for screening. Of those invited, 876 were subsequently screened for diabetes, and cardiovascular risk profiles of patients diagnosed after screening were also assessed. Prevalence of diabetes in patients with age as a sole risk factor was 0.2%. Prevalence of diabetes in patients with age and one or more other risk factor such as hypertension, obesity, or a family history of diabetes, was 2.8%. The authors reported the feasibility of screening for diabetes in the practice's population would take four hours a week for a year. About half this time would be needed to screen patients with risk factors other than age. More than 80% of patients newly diagnosed as having diabetes had a ten-year risk of coronary heart disease, 73% were hypertensive, and 73% had high cholesterol. The authors concluded that screening for diabetes in general practice by measuring fasting blood glucose is feasible but has a very low yield in patients whose only risk factor for diabetes is being over 45 years of age. In addition, they added that screening in a low risk population would best be targeted at patients with multiple risk factors.

Unconventional settings, outside of the general medical practice, are an underutilised source to attempt to identify people with undiagnosed diabetes. Howse, Jones and Hungin (2011) investigated the feasibility of using optometry practices as a setting to screen for diabetes. Adults attending high street optometry practices in northern England who self-reported at least one risk factor for diabetes were offered a RBG test. Those with raised RBG levels were asked to visit their GP for further investigations. Of the 1909 adults attending practices for sight tests, 68.2% reported risk factors for diabetes, of which 76.9% had RBG measurements taken. Of these, 318 (31.7%) were found to have a RBG level of ≥ 6.1 mmol/l, suggestive of the need for further investigations. Of these, 1.6% of previously undiagnosed individuals were diagnosed with diabetes or pre-diabetes as a result of the service. The authors suggested that even if they had refined the number of risk factors for inclusion which would have

reduced those requiring screening by half, the screening programme would have still identified nearly 70% of the new cases of diabetes and pre-diabetes (Howse, Jones, & Hungin, 2011a). The results demonstrated that screening in optometric practices provides an efficient opportunity to screen at-risk individuals who do not present to conventional medical services, and is acceptable and therefore appropriate suggesting that optometrists represent a skilled resource that could provide such a screening service. The success of this study represents how transferable such a screening programme can be and opens up the possibility of testing such a programme in other alternative settings.

A few small studies have examined the utility of the emergency department in screening for T2D. To determine if screening for undiagnosed T2D and pre-diabetes was feasible in an Australian emergency department, Jelinek and colleagues estimated the prevalence of T2D and pre-diabetes (Jelinek et al., 2010). A convenience sample of adult patients were screened with finger-prick RBG and HbA1c. Those with a result over 6.0 mmol/L and 6.0% were referred for an oral glucose tolerance test (OGTT). Those not attending for OGTT were contacted by phone, and interviewed about their reasons for not attending. Seven hundred and twenty-five patients were recruited. Of these, 135 had known T2D, subsequently leaving 590 to be screened; consequently, 210 screened positive. Of the 192 referred for OGTT, 77% did not attend despite several telephone reminders. Of the 45 completing OGTT, pre-diabetes was present in 17.8% and T2D diagnosed in 13.3%. Although the emergency department had a high prevalence of T2D, diagnosed and undiagnosed, with as much as half of the population possibly affected, it was concluded that opportunistic screening was not feasible due to the difficulties in patient follow up for diagnostic testing.

In 2012, NICE published preventative T2D guidance which highlighted a shift towards identifying at-risk individuals in different settings and supplying lifestyle interventions to reduce the numbers of people developing T2D (NICE, 2012). It suggested that screening would ensure those with undiagnosed T2D are made aware of their condition and receive appropriate treatment to help prevent complications. Dental surgeries were highlighted in the guidance as a suitable setting for encouraging people to have a T2D risk assessment (NICE, 2012).

Screening for Diabetes in Dental Settings

Diabetes is very relevant to dental professionals and to patients seen in the dental setting. As noted earlier in this chapter, diabetes as an established risk factor for periodontal disease, when poorly controlled, can complicate periodontal treatment outcomes (Mealey & Rose, 2008). Studies have revealed that periodontal disease is an early complication of diabetes (Lalla et al., 2007a, 2007b) and that pre-existing periodontitis predicts poor cardiovascular and renal outcomes in patients with established diabetes (Lalla, Kunzel, Burkett, Cheng, & Lamster, 2011).

Currently, population-based screening for diabetes is not recommended, though identification of high-risk persons and opportunistic screening for instance, during routine contact within the healthcare system is suggested as a more suitable strategy (Engelgau et al., 2000).

Improvements in the detection of dysglycaemia in undiagnosed individuals can be achieved by increasing the number of contact points from a range of healthcare professionals (Lalla et al., 2011). Identification of early diabetes can no longer be the sole responsibility of medical professionals, therefore considering the bi-directional relationship that has been found between diabetes and periodontal disease, and other oral manifestations that develop from diabetes, it is important to consider the role that dental care professionals can now play in this context.

Dentists have an important role in detecting and preventing oral and systemic diseases both because of their diagnostic and screening abilities and the frequency of patient visits (Tavares, Dewundara, & Goodson, 2012). Dentists already offer lifestyle advice to their patients as part of a preventive package of care. By extending this to cover general healthy eating and activity advice a broader reach of effect is offered to the patient; thereby addressing not only their oral health but also behaviours which may increase risk of T2D through the common risk factor approach. Traditionally, oral health promotion has focused on the care of the teeth and gums, in isolation from other health programmes. The Common Risk Factor Approach (CRFA) to health promotion takes a broader view and targets risk factors common to many chronic conditions and their underlying social determinants. The key concept of this approach is that rigorous action against common health risks and their underlying social determinants will achieve improvements in a range of chronic health

conditions more effectively and efficiently than isolated, disease-specific methods (Sheiham & Watt, 2000).

A large number of patients with periodontal disease visit a dental provider regularly for periodontal maintenance, again suggesting that the dental office may be an opportune site for systemic health screening (Rosedale & Strauss, 2012). Recent figures show that 61% of adults in England, 60% in Northern Ireland and 69% in both Wales and Scotland now attend their dentists regularly. In 1978, the figure was just 44% in England and 39% in Wales. Half of adults say they visit their dentist every 6 months and 21% of adults say they visit their dentist annually. The UK is one of the most likely nations in Europe to visit their dentist for a check-up; the UK was ranked second after only the Netherlands (Oral Health Foundation, 2017). Previously, it had also shown that a large proportion of the UK population see a dentist at least once a year and healthcare utilisation patterns indicate that individuals tend to seek routine and preventive oral health care more often than routine and preventive medical healthcare (Glick & Greenberg, 2005). The dental visit is therefore an excellent opportunity for dentist professionals to offer screening to their patients. They may be able to detect undiagnosed diabetes early by recognising features of gingivitis and periodontitis that are consistent with diabetes-related conditioning of periodontal responses to plaque. In a survey examining health and nutrition, researchers revealed that simple periodontal measures that are only available in the dental setting, and risk factors that are readily known by patients may well offer an opportunity to identify diabetes in patients who are undiagnosed (Borrell, Kunzel, Lamster, & Lalla, 2007).

It is now well known that the mouth may exhibit signs or symptoms of a poorly controlled or undiagnosed diabetes -related condition. It is also clear that there is a link between oral and systemic health, therefore there is support for the importance of the dental practitioner in detecting undiagnosed diabetes, and so the dental practitioner should become an integral part of the diabetes multidisciplinary team, enquiring about an individual's family history and the presence of signs and symptoms. Using periodontal disease is said to be a clinically effective and cost-effective screening method (Chauhan & Haslam, 2012).

Despite the known link between diabetes and periodontal disease, and that dental surgeries were highlighted in the 2012 NICE guidance as a suitable setting for encouraging people to

have a T2D risk assessment, dental practitioner involvement in diabetes care have not been officially incorporated into UK practice (Chauhan & Haslam, 2012). The UK Prospective Diabetes Study has shown that intensive glucose control which starts at the point of diagnosis is associated with reduced risk of microvascular complications over time (Holman et al., 2008). Dental practitioners should therefore be encouraged to promote diabetes screening so that earlier and more effective management of diabetes can be enabled, alongside the improvement of periodontal disease (Chauhan & Haslam, 2012).

It has long been argued that there is a need to address the relationship between general health and oral health in the dental setting (Page, 1998). Research has shown that general dentists lack knowledge about diabetes and the effects of diabetes on periodontal health (Al-Khabbaz & Al-Shammari, 2011; Al-Khabbaz, Al-Shammari, & Al-Saleh, 2011; Kunzel, Lalla, Albert, Yin, & Lamster, 2005). Dentists have an ethical obligation and a duty of care to protect the well-being of their patients. A screening procedure to detect a serious, underlying, undiagnosed systemic condition, and that does not cause any harm to the patient, is in the patient's best interests (Sultan, Warreth, Fleming, & MacCarthy, 2014).

A patient with diabetes may have a number of specific direct implications for the dental professional:

- Patients with (particularly T1D) diabetes may be at risk of hypoglycaemic episodes while attending the dental surgery
- People with diabetes are at higher risk of oral disease, particularly periodontitis, and particularly if their diabetes is poorly controlled
- Patients with undiagnosed diabetes may present at the dental surgery and provide an opportunity for referral for opportunistic screening based on the presence of periodontal disease and other diabetic risk factors
- Patients with diabetes may experience some improvement in their glycaemic control following successful periodontal treatment (Casanova, Hughes, & Preshaw, 2014).

Recent studies suggest that the majority of dentists feel it is important and that they are willing to conduct screening for medical conditions that patients are unaware of (Greenberg, Glick, Frantsve-Hawley, & Kantor, 2010). It must be made clear that the dentist's role stops here. A reliable diagnosis of diabetes mellitus cannot be made by a glucometer and furthermore the dentist is not covered legally to make such a diagnosis. The dentist has an

obligation to refer a patient who tests positive to an appropriate medical service for formal diagnosis and management (Sultan et al., 2014).

Dentists' views on screening for diabetes in dental settings

Esmeili, Ellison and Walsh (2010) aimed to determine general dentists' attitudes and practices related to patients with diabetes. A survey on 265 dentists randomly selected in California showed that 61% believed that addressing diabetes was important to their role as a dentist, 86 % advised patients with diabetes about periodontal risks, 18 % provided diabetic-related services, 47% reported they knew how to assess for diabetes, and 42% felt well prepared to intervene with patients with diabetes. Adjusting for number of patients with diabetes and adult patients seen in the past month, dentists' formal training in diabetes assessment and management, and belief in the importance of their role as a dentist to intervene with patients with diabetes were both significant factors in providing services for patients with diabetes (Esmeili, Ellison, & Walsh, 2010). Similarly, dentists' formal training and belief in the importance of their role were both significant factors in advising patients with diabetes about periodontal risk associated with diabetes. The authors concluded that formal training and personal beliefs were important factors related to dentists' behaviour toward patients with diabetes in the dental setting. The finding that over half of the dentists surveyed believed that intervening with patients with diabetes was important to their role as a dentist, is encouraging in that the will to participate in addressing this important health issue in the dental setting appears to exist, however, fewer than half believed that they had enough knowledge to assess and intervene with patients with diabetes in the dental setting, suggesting the need for intervention to increase or update dentist's knowledge of diabetes.

Patients' views on screening for diabetes in dental settings

In order to implement screening in the dental setting, an understanding of patient attitudes in different key dental settings is essential. Greenberg, Kantor, Jiang and Glick (2012) assessed patient attitudes toward medical screening in a dental setting using questionnaires with eight five-point response scale questions given to a convenience sample of adult patients attending an inner-city dental school clinic and two private dental practice settings. The majority of respondents were willing to have a dentist conduct screening for heart disease, high blood pressure, diabetes, human immunodeficiency virus infection, and hepatitis infection. They were also willing for the dentist to discuss the results immediately, provide oral fluids, finger-

stick blood, blood pressure measurements, and height and weight (Greenberg, Kantor, Jiang, & Glick, 2012a). Patients were also willing to pay up to 20 US dollars for these screening tests. Respondents reported that their opinion of the dentist would improve regarding the dentist's professionalism, knowledge, competence, and compassion by carrying out these tests. Results additionally showed that the test not being done by a physician was ranked as the least important potential barrier to being screened by a dentist. These recent results show that patients are willing to participate in chair side medical screening in a dental setting. The authors concluded that screening for various medical conditions in this setting is an approach that could be effective in disease prevention and control which integrates health professionals across disciplines.

These findings are invaluable to the progression of such a strategy as patient and dental acceptance of medical screening in a dental setting is a critical element to successfully implement screening for diabetes in the dental setting. However, patient and dental professional attitudes and willingness to participate in screening involve only anticipated responses and does not examine dental provider and dental patient attitudes and experiences regarding the actual implementation and receipt of diabetes screening at the dental visit. This information is vital to be able to inform diabetes screening practice in the dental setting, and for it to become an accepted routine practice. Therefore, Rosedale and Strauss (2012) examined patients and dental providers' experiences of diabetes screening using the collection of gingival crevicular blood and finger stick blood for HbA1c testing during the periodontal visit. Patients attending a periodontal clinic were screened for diabetes; 102 patients gave gingival crevicular blood samples, and 120 patients gave finger stick blood samples to be sent to the laboratory for analysis. Results of the tests were subsequently sent to patients directly from the laboratory. The results of the study showed that both patients and the dental providers believed that the dental visit was a good place to be screened for diabetes. Dental providers were willing to collect blood samples for testing, while most patients appreciated being provided with diabetes screening and the time-saving manner in which it was delivered (Rosedale & Strauss, 2012). Both dental providers and patients preferred gingival crevicular blood as a method of sample collection for screening. This was seen as simpler during the periodontal examination where there is considerable bleeding on probing, so it was seen as more convenient and less invasive. Overall, patients and providers found the dental visit to be an opportune site for screening for diabetes.

Friman and colleagues conducted interviews following diabetes screening at a dental clinic in Sweden. The interviewees described the dental care service as providing continuity and they expressed a wish to have regular medical screenings at their regular dental appointments to identify risks of cardiovascular disease and diabetes. However, they expressed that it was important for the dental care staff to have the necessary medical knowledge. They also wanted good co-operations between the dental and health care services, with clear feedback to the patients about both positive and negative results and, when appropriate, referrals to the health care service (Friman et al., 2015).

Research into diabetes screening in dental settings is being conducted more and more. In a recent study conducted in the USA, Bossart and colleagues assessed the effectiveness of diabetes screening using an instant A1c analyser, a diabetes risk questionnaire and periodontal findings at point of care by a dental hygienist. Point-of-care HbA1c screenings by dental hygienists were found to be effective and convenient for identifying undiagnosed prediabetes (Bossart et al., 2016). However, there was no relationship between the diabetes risk scores and HbA1c results indicating that it may not have been a desirable screening questionnaire for use in the dental setting.

In another US based study, Herman and colleagues screened dental patients for prediabetes and diabetes using information that was readily available to the dental practitioner and a random capillary blood glucose test to assess risk. A sample of participants then went on to receive a definitive diagnosis using A1c information. The results showed that patients at risk of prediabetes or diabetes could be identified rapidly using the risk questions alone or with the random capillary glucose test (Herman, Taylor, Jacobson, Burke, & Brown, 2015). This study did not go beyond identifying those at risk of diabetes and the HbA1c test was not administered during the dental visit. They also did not use a validated risk questionnaire to assess diabetes risk. Therefore, it would be interesting to see if using a two-step screening approach involving a self-report risk questionnaire during the dental visit would be acceptable and successful, and whether those identified as at risk of diabetes, acted on this risk information.

It has been noted that US patients are more willing to let dentists perform a screening test that yields immediate results and are less willing to have a screening test done if the samples have

to be sent out to an outside laboratory (Greenberg et al., 2012a), as seen in the procedure used in the study discussed above. Genco and colleagues (2014) aimed to determine whether point-of-care measurement of HbA1c from a finger-prick blood sample, in combination with use of the ADA Diabetes Risk Test; demographic and health data; and periodontal evaluation, would be useful in establishing a feasible method of screening for undiagnosed diabetes and prediabetes in dental practices. They found that their results also supported the notion that screening for prediabetes and diabetes is feasible in a dental office, with acceptance by the dentist, patients' physicians and patients (Genco et al., 2014). Again, this study did not follow-up patients found to be at risk of diabetes, so it was not known whether the screening test had an effect on subsequent behaviour.

Wright, and colleagues aimed to assess the feasibility of implementing a T2D risk screening pathway in dental settings using the NICE guidance tool. The study was carried out over two weeks in June 2013 in London, UK. The validated tool in the NICE guidance was used to determine risk. This included a questionnaire and BMI measurement used to determine a risk score. Patients were rated low, increased, moderate or high risk; patients who were moderate or high risk were referred to their GPs for further investigation. Participating dental teams were asked to nominate a member who would be responsible for overseeing the screening and training the other team members. A total of 166 patients took part in the pilot; twenty-six low risk patients, 61 increased risk patients, 49 moderate-risk patients and 30 high-risk patients were identified during the pilot. Fifteen of the 49 patients identified as moderate-risk and 6 of the 30 high-risk patients had visited their GP to discuss their type 2 diabetes risk in response to the screening. The pilot suggested that people at risk of developing T2D could be identified in primary, community and secondary dental care settings (Wright, Muirhead, Weston-Price, & Fortune, 2014).

In this single UK study carried out in GPs in London using a self-report risk measure, it was found that notwithstanding the manpower challenges facing dental teams and the fairly low uptake of further screening by patients, the identification of diabetes in dental practices was possible. One explanation for the low uptake of further diagnostic testing in this study could be the fact that patients tend to judge the severity of the illness by cues such as the complexity of the diagnostic tool used. In the case of diabetes in particular, previous work (Parry, Peel, Douglas, & Lawton, 2006) showed that diabetes patients used their diagnosis journey to judge how serious their diabetes was; the more complex the diagnosis, (where for

e.g. the diagnosis was made by a hospital consultant rather than a GP) the more serious patients thought was their diabetes. On the basis of these findings, it was reasoned that supplementing a self-report diabetes risk assessment with a more invasive, instant HbA1c blood test might improve the uptake of further formal GP testing.

These recent studies demonstrating the success of screening for diabetes in dental settings has provided evidence to base future studies on. Current recommendations for screening for diabetes in the UK suggests a step-wise method like those mentioned above. Using more than one screening test to assess risk is helpful and allows further screening tests to be targeted towards those identified as at risk of developing diabetes. A future study could utilise a non-invasive screening test first such as a self-report risk questionnaire, before administering an invasive test, such as an HbA1c test. It could also involve a point of care test where results would be instantaneous rather than having to inform patients of their result at a later date. A further study could also be conducted within a dental setting but not be conducted by a dental practitioner whose time is often short when with a patient already. Finally, there is scope for follow-up of patients found to be at risk of diabetes, to see if they acted on the screening information they received. These issues will be the basis for the rationale for the studies that follow in this thesis; the purpose of which will be to investigate these issues.

To conclude, dentists and patients alike have a favourable attitude toward point-of-care medical screening in the dental office; dentists are willing to incorporate it into their practice and patients are willing to participate in chairside medical screening. The 2010 Patient Protection and Affordable Care Act aims to slow increasing health care costs while improving the health care delivery system with a strong emphasis on prevention and primary care (Greenberg, Kantor, & Bednarsh, 2016; Greenberg, Thomas, Glick, & Kantor, 2015). These recent studies demonstrate that screening for diabetes in dental settings is acceptable by both patients and dental professionals, and when considering how important it is to diagnose diabetes early to prevent diabetes-related complications, there is clear support that diabetes screening in the dental setting is both timely and overdue.

Conclusion

In conclusion, this literature review has shown that screening for diabetes is unlikely to cause psychological harm, it may be helpful in identifying people at risk of diabetes or pre-diabetes,

it can take place in a non-routine setting such as the dental practice and can probably involve the use of easy to use tools such as instant HbA1c measures and a self-report risk questionnaire.

The next chapter presents the results of a systematic review on how risk of disease should be communicated in order to increase the chances that people will act on the screening information they have been given.

Chapter 3

What are the most effective of individualised risk communication strategies to increase screening participation or its psychological predictors? A systematic literature review

Introduction

It is important to explore key opportunities to detect disease and carry out screening programmes. By providing alternative locations as a setting for screening, we can widen access to those at risk who do not access conventional healthcare settings for whatever reason. The dental setting is somewhere we can offer screening and is an underutilised source. As seen in chapter two, research has shown that screening for diabetes in this setting is acceptable to both patients and General Dental Practitioners (GDPs). We are however unaware of the sort of patient who will pursue screening and those who will need support after initial screening, so the psychological predictors of subsequent diagnostic testing are unknown and needs to be explored. A systematic review is a high-level overview of primary research on a particular research question that tries to identify, select, synthesize and appraise all high quality research evidence relevant to that question in order to answer it. Therefore, a systematic review might be a good way to address the issue of identifying what will most likely make an individual pursue subsequent diagnostic testing following screening by attempting to identify the most effective way to communicate an individuals' risk of a particular condition. This chapter therefore describes a systematic review that was conducted to address this issue. By addressing this issue, an intervention was designed so that a dental patients risk of diabetes could be communicated in the best possible way to ensure that diagnostic follow-up would be adhered to.

The results of the work presented in this chapter have been published in 'Health Psychology Research', and the paper appears in appendix one.

Background

Social cognition models (SCMs) are used to help understand, predict and change health-relevant behaviours. A considerable amount of research in health psychology has focussed on the role of social cognitive factors and their ability to predict health behaviour. The reason for this is that a significant proportion of mortality from the leading causes of death in the

industrialised world is due to particular behaviour patterns, of which are certainly modifiable (Webb, Sniehotta, & Michie, 2010). Individuals can make a contribution to their own health and wellbeing though adopting particular health-enhancing behaviours (e.g. screening), and avoiding health-compromising behaviours (e.g. smoking). The factors which underlie health behaviours have been targeted by interventions to change the prevalence of such health behaviours and improve health at an individual and a population level, and to understand the reasons why individuals perform such a variety of health behaviours. Several models which have been designed in health psychology to specifically predict health behaviour focus on the notion of threat or risk perception (Lopez, Tolley, Grimes, & Chen-Mok, 2009). By this, SCMs seeking to predict adherence to health behaviours suggest that people consider their risk for a particular condition, whether it is expressed as their perceived risk, perceived susceptibility, or their perceived severity for developing a disease, before engaging in any health behaviour. Therefore, risk is an important concept to examine, so that an individual's understanding of their own risk for a particular disease or condition can be targeted to inform the decision to undergo screening.

There is a diverse range of tests that can be used to identify individuals and groups at 'high risk' of developing various diseases or conditions. With the development of screening programmes, many of these tests and procedures aim differentiate between apparently well people who probably have a disease, and those who probably do not, or aim to highlight a risk of disease rather than intend to diagnose a disease or condition (Edwards et al., 2006).

Some screening programs provide information about population or 'average' risks of developing a disease to discuss or inform decision-making about attending for screening, whilst others look to motivate people to attend for tests which are alleged to be in their best interests (Edwards et al., 2013). Another way to target screening uptake is to provide information which is more personally relevant to the user in question. 'Individualised risk communication' also known as 'personalised risk communication' is based on the individual's own risk factors for a condition (such as age or family history) (Edwards et al., 2013). In this case, risk can be comprehensively calculated from an individual's risk factors using formulae derived from epidemiological data. An example of this would be the Gail model for predicting the risk of developing breast cancer; here a risk score is given or presented as an absolute risk, the risk of developing a disease over a time period (Gail et al., 1989), or an individual's relative risk; comparison of risk to others, can be categorised into, for example, above average, average or

below average risk, which is less comprehensive. Risk information can also be more simply presented, for example, where a list of personal risk factors is discussed and used as the basis for intervention (Rothman & Kiviniemi, 1999). When presented in this way, it is expected that because the information is thought to be more applicable to the individual, individualised risk communication may be more useful when deciding whether or not to participate in screening (Edwards et al., 2006).

Given the importance of risk and risk communication in healthcare (Moher, Liberati, Tetzlaff, & Altman, 2009; Waldron, van der Weijden, Ludt, Gallacher, & Elwyn, 2011), it is important to identify the most effective strategies for risk communication at an individual level. Understanding however of how best to present and discuss risks and benefits of health care in general, and screening in particular, for an individual is still limited. Effective risk communication can improve awareness of health risks and promote risk-reducing behaviour in support of health promotion and disease prevention (Waldron et al., 2011).

There is a variety of ways risk information can be communicated to patients. Numerical expressions can be presented in percentages, natural frequencies or numbers needed to treat (Gigerenzer & Edwards, 2003), whilst graphical representations can also be displayed. These can involve the use of bar graphs and pictograms or icon arrays (Lipkus & Hollands, 1999). There is a need for the risk information to be presented in a simple and balanced way, and it is important to communicate the risk appropriately and effectively, as poor representation of risk information may result in sub-optimal choices and treatment (Edwards, Elwyn, Covey, Matthews, & Pill, 2001; Lipkus & Hollands, 1999). Individualised risk communication has been incorporated into several healthcare interventions, including the areas of treatment, prevention and screening. Therefore, it is vital to look at the effectiveness of interventions that aim to increase screening through individualised risk communication interventions.

A recent updated systematic review of forty-one studies by Edwards and colleagues, aimed to assess the effects of different types of personalised risk communication for consumers making decisions about taking screening tests, and concluded that there was weak evidence, consistent with a small effect, that personalised risk communication in which a risk score was provided (6 studies) or the participants were given their categorised risk (6 studies), increases uptake of screening tests (Edwards et al., 2013). They also found that the interventions seemed to increase knowledge and may increase accuracy of risk perception in the trial participants.

This systematic review successfully answered the question as to whether individualised risk communication is more effective than generalised risk communication, and also found that when the personalised risk information disclosed was more detailed, the uptake of tests was lower than when the risk communication was less detailed or numerically unspecific (i.e. when categorised into risk groups). However, its focus was not on assessing how best to present and communicate individualised risk in terms of the format (e.g. such as written, over the telephone or verbally in person, or about the overall presentation and detail). Rather, the purpose of their review was to assess the effects of personalised risk communication on informed decision making by individuals taking screening tests. Additionally, proxies of screening uptake were considered in the review, but the theoretical background of the reviewed studies was not investigated.

In a systematic review looking specifically at communicating cardiovascular risk (Waldron et al., 2011), the aim was to compare different interventions used to communicate cardiovascular risk in order to identify effective communication strategies, and assess their impact on patient related outcomes. Although heterogeneity in study design and outcomes were found in a review of fifteen studies, the results from individual studies suggested that presenting patients with their cardiovascular risk in percentages or frequencies, using graphical representation and short timeframes, is best for achieving risk reduction through behaviour change. However, this review focused on cardiovascular risk only and did not attempt to explore whether theory-based interventions were more effective than atheoretical work in eliciting behaviour change or whether certain presentation details such as who delivered the risk information and whether it was simple or complex details that were given were best. If the purpose of risk communication is to lead to behaviour change such as screening uptake, then theoretical work, such as social cognition models designed to inform behaviour change interventions may be useful in designing risk communication interventions.

Given the importance of risk communication in healthcare (Rothman & Kiviniemi, 1999), it is important to identify the most effective strategies for risk communication at an individual level. Understanding however of how best to present and discuss risks and benefits of health care in general, and screening in particular is still limited. The previous systematic reviews though informative, have not sought to explain why less detailed risk information (Edwards et al., 2013) presented in graphs, scores or categories (Waldron et al., 2011) is effective in

maximizing screening uptake. Given that social cognition models describe key cognitions, such as risk and susceptibility, and their inter-relationships in the regulation of behaviour, individualised risk communication interventions informed by social cognition models may lead to different outcomes than those not informed by social cognition models, such as, the extent to which an individual will respond to the threat of risk. If the purpose of risk communication is to lead to behaviour change, then psychology theory such as, for example, social cognition models designed to inform behaviour change interventions, may be useful in understanding what combinations of individualized risk communication (IRC) components work best.

Following the aims, approaches and the findings from these previous reviews, the purpose of this study was to identify the most effective ways of presenting risk information to subsequently maximise screening uptake. Additionally, the present review evaluated whether individualised risk communication affects psychological proxies that have been proposed, through theoretical models, to mediate the increase in screening uptake.

Aim:

The aim of this narrative systematic review is to evaluate the most effective way to communicate individualised risk information to maximise either actual screening uptake or psychological predictors of screening uptake. This aim therefore addresses the first research question given in chapter 1:

1. What is the most effective way to communicate individualised risk information to increase screening participation or its psychological predictors?

Objectives:

- Identify RCT studies whereby the communication of individualised risk information is delivered for the purpose of increasing screening participation;
- Identify effective individualised risk communication strategies to maximise either actual screening uptake or potential psychological predictors.

Research Question:

What is the most effective way to communicate individualised risk information to maximise either actual screening uptake or the psychological predictors of screening uptake?

Method:

Protocol:

The review is laid out in accordance to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement. A review protocol was used as a template in order to collect relevant information from papers for inclusion.

Eligibility Criteria:

For studies to be included in the review, they were required to meet certain criteria.

Types of studies

Papers where individualised risk communication was defined as conveying probabilistic information intended to support decision-making with an educational component of either a disease, personal risk factors, inheritance of susceptibility, benefits and limitations of tests, risks of testing, limitations of prevention, or surveillance were sought to answer the review question. Studies were considered for inclusion if they evaluated interventions that were randomised controlled trials (RCTs). It is well recognised that some research designs are more powerful than others in their ability to answer research questions on the effectiveness of interventions. The randomised controlled trial (RCT) is considered to provide the most reliable evidence on the effectiveness of interventions because the processes used during the conduct of an RCT minimise the risk of confounding factors influencing the results. Because of this, the findings generated by RCTs are likely to be closer to the true effect than the findings generated by other research methods (Evans, 2003).

Types of participants

Studies that either used people facing real life decisions or where participants were studied in hypothetical situations about whether to undergo screening were included. They could be individuals making decisions alone or on another's behalf (for example, for a young child), or couples making decisions together. The screening activities had to involve an investigation performed by a health professional for example, mammography, cervical 'Papanicolaou' smears, colorectal cancer screening, prostatic cancer screening (PSA test), antenatal screening, genetic screening (for example, breast cancer gene testing), cardiovascular risk screening and neonatal screening.

Types of interventions

Studies were included where interventions were providing information on individualised risk, such as an individualised risk score or individual actual risk information, categorisation of risk status based on these estimates such as, high, medium, or low risk status, such as for colorectal cancer, or a discussion of personal risk factors relevant to the screening decision, such as the individual's own characteristics being taken into account when assessing their actual risk or heightened risk status relative to others, for example, risk factors for breast or prostate cancer that are relevant to the individual. Individualised risk communication could be delivered via oral, written, video, or via electronic media.

Studies with interventions providing information on individualised risk compared with another individualised risk arm, a control arm receiving usual care or generalised risk information, including average or population risk estimates (such as risk of breast cancer), general information on risk factors, and general encouragement to acknowledge risks or change risk behaviour were considered for inclusion. Studies were rejected if general, rather than personalised risk communication was the main basis of the intervention.

Types of outcomes

Studies were required to measure and primarily focus on behavioural outcomes such as uptake of screening tests. Additionally, studies were considered for inclusion if there was a theoretical basis to the intervention, such that it focussed on a particular social cognition model or particular model components such as knowledge about a disease or screening test, motivation, fear or coping to predict screening participation. In order to address the research question, if screening uptake was not measured, studies were required to measure one or more psychological factors or predictors of screening uptake such as knowledge, fear or screening intention.

It was decided that papers were to be excluded if they were published on or before 31st December 2005, as we did not want to include papers that were featured in the systematic review by Edwards 2006 where the search strategy included papers published up until this date. It was assumed that all relevant material up until this date was covered in his systematic review.

Finally, studies were required to be available in the English language as translation into English was not feasible within the timeframe of this review.

Information Sources:

To access a large number of possible studies, five electronic databases were systematically searched: EMBASE, MEDLINE, PsycINFO (using Ovid), Web of Science and PubMed. Comprehensive search strategies were devised and conducted in July 2012, aiming for a high recall of literature which were low in specificity in the field of risk communication in screening, and social cognition model elements. Subject heading and keyword searches were utilised, and were adapted to each of the databases used. A manual search was also conducted of the journals and authors encountered most frequently in the field. Additionally, the reference lists of included papers and past systematic reviews in the area of risk communication were also searched to look for any relevant studies for inclusion that were not found in the electronic search.

Search:

To conduct effective searches, comprehensive search strategies were developed with the assistance of an Information Systems expert for each database which included MESH heading and key words. These were chosen to cover areas regarding screening tests, risk, social cognition components, and communication. Boolean operators were utilized to identify the most relevant literature.

Study Selection:

Eligibility assessment was performed independently by two reviewers. Titles and abstracts of articles identified from the systematic search were examined in relation to the relevance to the topic and duplicates were removed at this stage. The full texts of articles were then screened to identify whether or not they were eligible, and those not meeting the inclusion criteria were excluded at this stage, leaving a final number of studies for inclusion in the systematic review.

Data Collection Process:

Data were extracted from the reports by two independent reviewers (KB and KA) to minimise reporting bias. Authors of the included articles were contacted directly if questions arose about

the reported data. A search protocol data sheet was developed and used to extract all important and relevant information from the studies.

Data Items:

Detailed information was extracted from each of the studies, primarily on the characteristics of the participants (such as gender, age, and ethnicity, if available), the characteristics of the intervention (including format, type, presentation and delivery mode of the risk information) and comparison groups, and the types of outcome measures assessed (including screening outcomes and psychological predictors of screening outcomes).

Risk of Bias in Individual Studies:

To ascertain the validity of the eligible interventions, two reviewers worked independently, to determine the adequacy of the studies included at the study level using the Cochrane's Risk of Bias tool. No studies were excluded from the review on the basis of their risk of bias.

Summary Measures:

The primary outcome measured was actual screening uptake. Secondary outcomes measured psychological predictors of screening uptake such as knowledge, perceived risk and intentions. Observed and total numbers from studies with dichotomous outcomes such as screening uptake, and means or mean change and standard deviations for studies with continuous outcomes, such as knowledge and cancer worry, were considered in order to arrive at the narrative conclusion.

Synthesis of Results:

Due to the heterogeneous nature of the studies included in this review, in terms of the wide variety of dependent variables and the nature of the designs, it was not deemed possible to perform a meta-analysis on the full set of studies, and meta-analyses on a small number of subsets was deemed unworthy. For example, the interventions that measured actual screening uptake at 1 year follow up were heterogeneous and not comparable, with the interventions being 'computer based risk assessment' compared with a 'mailed risk assessment' intervention or an 'individualised risk score' compared with a 'discussion of risk factors'. Thus, it was thought to be more appropriate to perform a narrative synthesis on all interventions. No meta-analysis was performed.

Risk of Bias across Studies:

No further analysis was performed to assess risk of bias as the Cochrane's risk of bias tool was considered to be sufficient.

Additional Analyses:

There were no additional analyses performed in the systematic review.

Results:

Study Selection:

Eligibility assessment was performed independently by two reviewers. Disagreements between reviewers (KB and KA) were resolved in a discussion. Figure 1 shows the PRISMA flow diagram of study selection. The systematic search revealed a total of 7408 articles. Each article title and abstract was examined in relation to the relevance to the topic, which resulted in a list of 107 articles retained at this stage. The full texts of articles were then read to identify whether or not they met the inclusion criteria, and 86 studies were excluded at this stage, with a total of 21 articles being chosen as relevant.

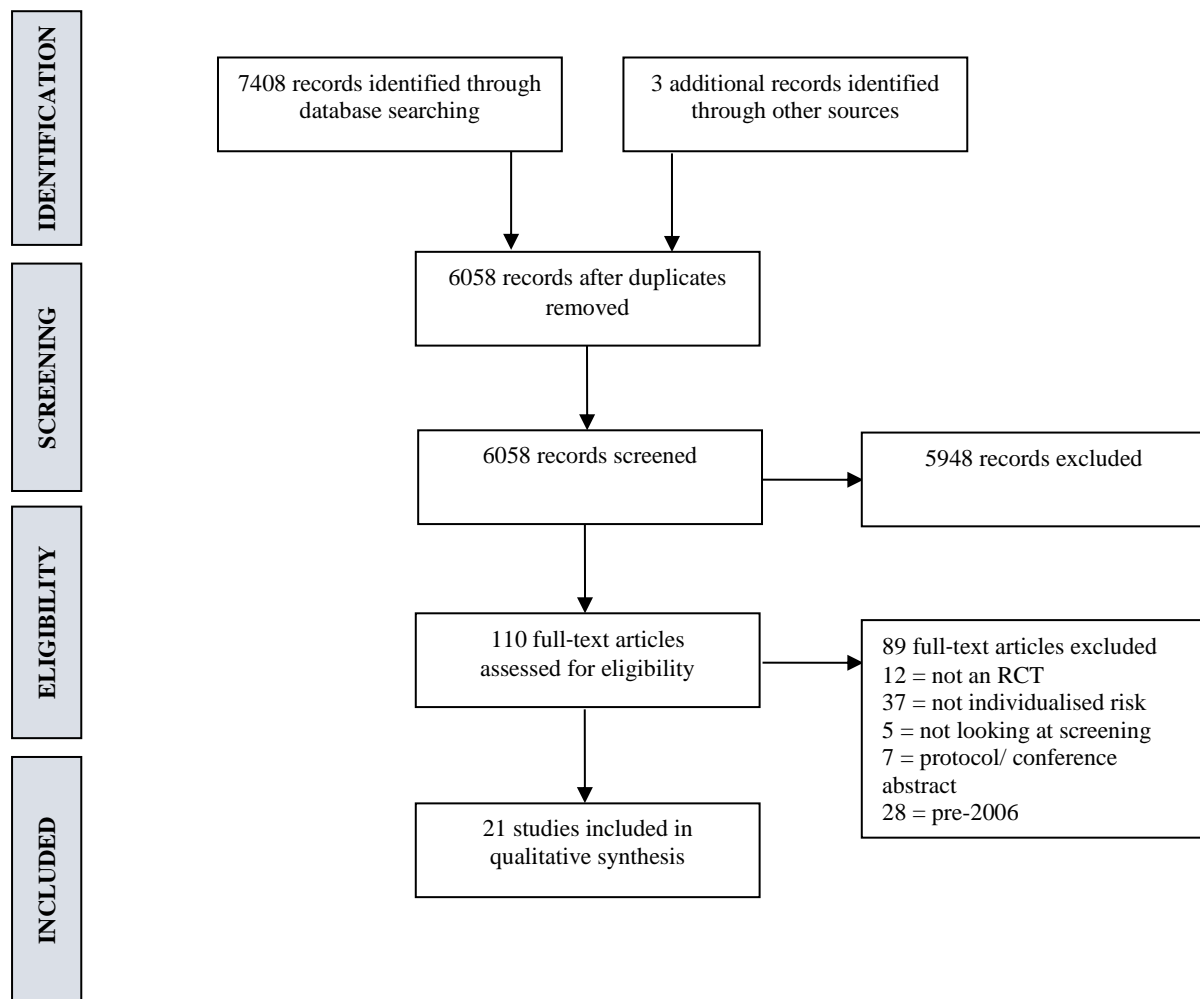


Figure 1 – PRISMA flow diagram

The main elements of each study were extracted (such as intervention content and outcome variables). Each of the articles was summarised to highlight the main issues of interest, and the data can be found in Tables 1 and 2. Although 21 articles were identified as relevant, in some cases, articles were reporting the same study and data as another. There were three studies which were each reported in two articles, therefore in total, there were 18 studies. Table 2 reports articles where the same data and study is reported together.

Study Characteristics:

Table 1 contains details of the features of the 21 articles included in the review.

Participants and Settings:

The studies had a total of 22,557 participants, with the number of participants in each study ranging from 262 to 5500. In terms of gender, overall, the number of women included was higher than the number of men, with 16,064 women compared to 4,716 men. The majority of studies recruited healthy participants whilst seven studies recruited participants thought or known to be at higher risk than average for the screened condition (Bodurtha et al., 2009; Bowen, Burke, Culver, Press, & Crystal, 2006; Glanz, Steffen, & Taglialatela, 2007; Glenn et al., 2011; Lipkus & Klein, 2006; Manne et al., 2009; Rawl et al., 2012). The age of participants was from 18 years and above, with the highest reported mean age of around 74 years. Whilst some studies did not report the study setting, the majority of interventions were delivered in primary care or primary care practices, hospitals and clinics (n=7) or participants own environment (n=5). Finally, the majority of studies were conducted in the USA.

Interventions:

Table 2 gives details of the 22 interventions and the risk presentation information.

Interventions addressed several screening programmes and diseases. The most common was screening for colorectal cancer by colonoscopy, Fecal Occult Blood Test (FOBT) or Sigmoidoscopy. Second most common was screening for breast cancer or the breast cancer gene, where five studies looked to increase screening for breast cancer through mammography screening, One study specifically looked at screening for the breast cancer gene through genetic testing, and one study addressed screening through genetic testing and mammography. Further, one study addressed osteoporosis screening, one addressed prostate cancer screening and finally, two studies addressed a mixture of diseases or conditions and screening behaviours (e.g. blood glucose testing, blood pressure testing and cholesterol screening).

Table 1 - Study Details of included studies in the systematic review

Author, year, country	Setting	Participants	Intervention Arm(s)	Comparison Arm(s)	Follow-up	Outcomes	Additional Details / Comments
Allen et al. 2010 USA	Manufacturing industry worksites	625 male employees	1 intervention arm: Computer tailored decision-aid in the workplace	Control comparison arm - no intervention given.	3 months	<p>1. Decisional status - significantly more men in intervention arm had made a screening decision at follow up.</p> <p>2. Knowledge - increased significantly more in intervention arm.</p> <p>3. Decisional self-efficacy - no significant changes over time in either arm.</p> <p>4. Preference for control in decision making - no significant changes over time in either arm.</p> <p>5. Decisional conflict - reduced (non-significant) in intervention arm.</p> <p>6. Consistency between values and screening decision - no changes between arms over time</p>	<p>Although an ITT analysis was used, among the men in the intervention arm, men who actually used the decision aid were significantly more likely to have made a screening decision than non-users,</p> <p>Knowledge was significantly higher in the men who used the decision aid compared to non-users, and significantly greater decisional self-efficacy compared to the control arm.</p>
Bodurtha et al. 2009 USA	Women's health clinics	899 females in waiting rooms at women's health clinics	1 intervention arm: Computer generated tailored risk information on breast health	Control arm - participants received general non-tailored breast cancer prevention information.	1, 6 and 18 months	<p>1. Post intervention Mammogram - no significant differences between arms.</p> <p>2. Post intervention clinical breast examination - no significant differences between arms.</p> <p>3. Post intervention breast self-examination - no significant differences between arms.</p>	<p>Intervention based on HBM constructs.</p> <p>Women who reported breast cancer worry as 'often' or 'all of the time', reported greater mammography rates if they were in the intervention arm. Those who worried about breast</p>

						<p>4. Mammography intentions - no significant differences between arms.</p> <p>5. Perceived risk - no significant differences between arms.</p> <p>6. Breast cancer worry - no significant differences between the arms.</p>	<p>cancer only 'sometimes', reported lower mammography rates if they were in the intervention arm.</p> <p>There was a significant trend for women with high breast cancer worry to report higher perceived risk of breast cancer.</p>
<p>Bloom et al. 2006</p> <p>USA</p>	Participants own home	163 females - higher than average risk of developing breast cancer due to having a sister diagnosed with breast cancer at aged 50 or younger.	1 intervention arm: Tailored telephone counselling with personalised risk notification.	Control arm - received delayed intervention after follow-up.	6 months	<p>1. Mammography maintenance - no significant differences between arms.</p> <p>2. Clinical Breast Examination maintenance - no significant differences between arms.</p> <p>3. Perceived risk - no significant differences in risk overestimates between study arms.</p> <p>4. Breast cancer worry - no significant differences between study arms.</p> <p>5. Fruit and vegetable consumption - no significant differences between study arms.</p> <p>6. Reported physical exercise - significantly higher in the intervention arm.</p>	<p>Intervention based on TTM, HBM and Self- Regulation theory.</p> <p>More women in the intervention arm reported that they had reinforced their conviction to maintain good breast health than women in the control arm.</p> <p>The intervention was effective in reducing risk overestimates but only in women aged 50 and over.</p>
<p>Bowen et al. 2006</p> <p>USA</p>	NOT REPORTED	211 Ashkenazi Jewish women	2 intervention arms: Group psychosocial counselling with individualised	Control comparison arm - received delayed counselling intervention after follow-up.	6 months	<p>1. Perceived risk</p> <p>2. Cancer worry</p> <p>3. Awareness of genetic testing</p> <p>4. Interest in genetic testing</p>	<p>Trained genetic or health counsellors delivered the interventions.</p> <p>Results showed 2 significant predictors of change in interesting of</p>

			breast cancer risk assessment OR Individual genetic counselling with individualised breast cancer risk assessment.			<p>5. Candidacy for genetic testing</p> <p><i>Outcomes 1-5: there was a significant time and arm interaction, both intervention arms changed significantly more from baseline to follow-up, compared to the control comparison arm.</i></p> <p>6. Beliefs about genetic testing - 'Stigma' - no significant differences between study arms; 'Access' - no significant main effects of study arm or time, however, women in control arm increased their endorsement of beliefs about unrestricted access to testing compared to intervention arm women over time, whereas women in intervention arms decreased these beliefs compared to control arm women over time; 'Information flow' - no significant main effects of study arm, however, women in the control arm significantly decreased their belief about information flow more than women in the intervention arms did.</p> <p>7. General anxiety - NOT REPORTED.</p>	genetic testing: low levels of religious identity lead to low levels of change in interest, whereas low beliefs about free access lead to increased interest in testing.
Bowen et al. 2010 USA	General population	1366 Female participants	1 intervention arm: Stepped intensity intervention with personalised risk information	Control arm - received delayed intervention after follow-up.	1 year	<p>1. Quality of life - mental health scores improved significantly more so in the intervention arm.</p> <p>2. Cancer worry - NOT REPORTED</p> <p>3. Mammography uptake - significantly increased in intervention arm.</p> <p>4. Monthly breast self-examination - significantly increased in intervention arm.</p>	No results reported for two of the outcomes measured.

						<p>5. Knowledge - NOT REPORTED</p> <p>6. Interest in genetic testing - decreased in both study arms, but significantly more so in the intervention arm.</p>	
<p>Bowen et al. 2011</p> <p>USA</p>	General population	1454 females from general public	<p>1 intervention arm:</p> <p>Web-based intervention arm providing tailored and personalised risk information</p>	Control arm - received delayed intervention after follow-up	1 year	<p>1. Mammography screening - significantly increased in intervention arm compared to control arm.</p> <p>2. Breast self-examination - significantly increased in intervention arm compared to control arm.</p> <p>3. Quality of life - significantly increased in intervention arm compared to control arm.</p> <p>4. Genetic testing interest - significantly decreased in the intervention arm.</p> <p>5. Knowledge of breast cancer - higher knowledge was associated with higher screening rates at follow-up.</p> <p>6. Cancer worry - greater reduction in cancer worry was associated with higher screening rates at follow-up.</p> <p>7. Knowledge of genetic testing - higher gains in knowledge of genetic testing were associated with lower interest in genetic testing.</p>	<p>Intervention based on Self-Regulation Model.</p> <p>Due to level of risk, some women did not receive risk information via the website, rather in writing when attending the counselling session.</p>
Glanz et al. 2007		176 participants - 110 female,	1 intervention arm:	Comparison arm - General Health Counselling -	4 and 12 months	<p>1. Screening adherence - significantly higher in intervention arm at 4 months but not significant at 12 months.</p>	Intervention based on the Precaution Adoption Process Model.

Hawaii		66 male first degree relatives of patients with colorectal cancer.	Colon Cancer Risk Counselling - individual counselling session with personal risk profile	focussing on health promotion		<p>2. Risk comprehension - perceived risk increased in the intervention arm and mediated the change in screening adherence at 4 months.</p> <p>3. Cancer worry - NOT REPORTED</p> <p>4. Knowledge - knowledge and its general knowledge subscale mediated the change in screening adherence at 4 months.</p> <p>5. Health behaviours - significant drop in physical activity by participants in the intervention arm at 4 months; significantly fewer smokers in intervention arm compared to control arm at follow-up.</p>	Procedural errors reported - resulted in missing data for some of the behavioural outcomes.
Glenn et al. 2011 USA		1280 male and female first-degree relatives of colorectal cancer cases identified through the California Cancer Registry,	1 intervention arm: Personalised print intervention with personalised risk assessment.	Control arm - received a generic colorectal cancer pamphlet.	6 and 12 months	<p>1. Screening receipt - significantly higher in the intervention arm.</p> <p>2. Perceived risk - significantly higher in the intervention group; significant increases in perceived risk were observed in intervention participants who remained unscreened at 12 months compared to those who received screening.</p>	<p>Secondary analysis article, primary analysis unpublished.</p> <p>Results support the Risk Reappraisal Hypothesis.</p>
Harahi et al. 2008 UK	NHS Primary Care General Practices	2503 participants - 1090 female, 916 male functionally independent community-	1 intervention arm: Self-administered Health Risk	Control arm - no intervention	1 year	<p>1. Health risk behaviours - no significant differences between groups on all of the listed behaviours, except small significant difference in exercising >5 times a week in intervention arm.</p> <p>- physical activity -eating fat foods</p>	<p>No detail of what control arm received.</p> <p>The concurrent comparison arm differed significantly from the intervention arm at 1 year with</p>

		dwelling patients.	Appraisal for Older Persons	Concurrent comparison arm - usual care		<p>- smoking -eating fruit/fibre items</p> <p>-alcohol use -wearing seat belt</p> <p>2. Preventative care measures - no significant differences between groups on all the listed measures, except receipt of a pneumococcal vaccine which was significantly higher in the intervention group.</p> <p>-BP check - cholesterol measurement</p> <p>-FOBT - pneumococcal vaccine</p> <p>-blood glucose - dental check-up</p> <p>-influenza vaccine - mammogram</p> <p>-hearing check -vision check</p>	respect to cholesterol measurement within 5 year, fasting glucose within 3 years and influenza vaccine in the last year.
<p>Helmes et al. 2006</p> <p>USA</p>	Large network of Primary Care Physicians	340 female healthcare members	<p>1 intervention arm:</p> <p>In-person breast cancer risk counselling</p> <p>OR</p> <p>Telephone breast cancer risk counselling</p>	Control arm - Delayed intervention after the follow-up.	3 months	<p>1. Screening intentions - no significant difference between the three study arms.</p> <p>2. Cancer worry - decreased significantly more in the two intervention arms from baseline to follow-up than the control arm.</p> <p>3. Risk perceptions - significantly decreased from baseline to follow-up in two intervention arms.</p> <p>4. Interest in pursuing genetic testing - significant difference between the two intervention arms and control arm; control arm increased intentions whilst the intervention arms decreased intentions.</p>	<p>In-person counselling was more well received, preferred.</p> <p>The same genetic counsellor was used for the entire study in order to minimise any variation in counselling style or technique.</p>

Lipkus et al. 2006 USA	Medical Centre Risk Communication Laboratory	160 participants; 105 females, 55 males non-adherent to FOBT screening.	2 intervention arms: Tailored colorectal cancer 'absolute' risk factor feedback OR Tailored colorectal cancer 'absolute plus comparative' risk factor feedback.	Control arm - receiving general CRC risk factor information.	Immediately post intervention and 1 month.	<p>1. Screening Intentions - significantly higher in the higher comparative risk arm compared to the absolute risk arm and control arm, but not significantly different compared to the lower comparative risk arm; although this group was significantly higher than the absolute and control arm.</p> <p>2. Return of a completed FOBT screen - Those in the 'absolute plus comparative' intervention arm were more likely to return a completed test but, no significant differences overall between study arms.</p> <p>3. Cancer worry - no significant differences between study arms.</p> <p>4. Perceived severity - no significant differences between study arms.</p> <p>5. Perceptions of absolute risk - no significant differences between study arms.</p> <p>6. Perceptions of comparative risk - significantly higher in those told they had more than average number of risk factors than lower risk comparative arm and control arm.</p> <p>7. Barriers to screening - people reporting more barriers were less likely to return a completed FOBT.</p> <p>8. Attitudinal ambivalence - significantly stronger in the control arm. Significantly predicted return of a FOBT.</p>	<p>Perception of comparative risk analysis reran after removing cases in the comparative risk arm who incorrectly responded to the manipulation check, and was significantly higher in those told they had more than average risk factors than others, compared to the lower comparative risk arm, the absolute risk arm and the control arm.</p> <p>Perceived absolute or comparative risk was not related to ambivalence or intention.</p> <p>No significant differences between study arms on the evaluation of the risk factor information.</p>
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						<p>9. Strength of association between basic and lifestyle risk factors and colorectal cancer - no significant differences between study arms.</p> <p>10. Distribution of risk factors in the population - Those informed they had more than average compared with others reported higher number of risk factors than any other arm. People perceived others as having more risk factors than themselves but there was no significant difference between groups.</p>	
Manne et al. 2009 USA	General population	412 participants 248 females, 164 male siblings of colorectal cancer cases.	2 intervention arms: Tailored print OR Tailored print and tailored counselling call.	Control arm - Generic educational print pamphlet.	6 months	<p>1. Screening adherence - significantly higher in both intervention arms compared to control arm.</p> <p>2. Physician support for screening - not a significant moderator of treatment effect on screening effect.</p> <p>3. Perceived risk</p> <p>4. Perceived severity</p> <p>5. CRC knowledge</p> <p>6. Procedural knowledge</p> <p>7. Perceived preventability</p> <p>8. Decisional balance - the combined intervention arm was a significant predictor of decisional balance, significantly higher (more screening pros) in the combined intervention arm. Those with higher scores were significantly more likely to be adherent.</p>	Intervention based on TTM, HBM and Dual Process Theory.

Rawl et al. 2012 USA	Primary Care Clinics	556 participants 276 female, 280 male African- American not up to date with CRC screening	1 intervention arm: Computer- delivered tailored education and assessment.	Control arm - usual care, received a non- tailored CRC screening brochure.	1 week	<p>1. CRC knowledge - significantly greater increase in intervention arm.</p> <p>2. Perceived risk - significantly greater increase in intervention arm.</p> <p>3. Perceived barriers to FOBT - significantly greater decrease in intervention arm.</p> <p>4. Perceived benefits of FOBT - no significant difference between study arms.</p> <p>5. Self-efficacy for FOBT - no significant difference between study arms.</p> <p>6. Perceived barriers to Colonoscopy - no significant difference between study arms.</p> <p>7. Perceived benefits of Colonoscopy - significantly greater increase in intervention arm.</p> <p>8. Self-efficacy for Colonoscopy - no significant difference between study arms.</p>	Intervention based on HBM constructs.
*Rubinstein et al. 2011 USA	Primary Care	4248 participants, 2974 females, 1274 male primary care patients	1 intervention arm: Web-based familial risk assessment tool for 6 diseases.	Control arm - Received standard prevention messages for the same 6 diseases.	6 months	<p>1. Screening adherence - no significant differences between the percentage of participants moving from non-adherent to adherent to any of the cancer screening tests or methods in any of the familial risk categories. Participants in both study arms equally increased their adherence to risk-based</p>	The population under study had far higher screening adherence than a national sample.

						<p>screening but there were no significant differences between study arms.</p> <p>2. Consultation with specialist about their cancer risk - no significant differences between groups or risk categories.</p>	
<p>*Ruffin et al. 2011</p> <p>USA</p>	Primary Care	<p>4248 participants,</p> <p>2974 females,</p> <p>1274 male primary care patients</p>	<p>1 intervention arm:</p> <p>Web-based familial risk assessment tool for 6 diseases.</p>	<p>Control arm -</p> <p>Received standard prevention messages for the same 6 diseases.</p>	6 months	<p>1. Screening behaviour - Cholesterol screening: the intervention arm was significantly less likely to have had a cholesterol test in the last 3 years compared to the control arm. Blood pressure testing: no significant differences between study arms. Blood glucose testing: no significant differences between study arms.</p> <p>2. Behaviour changes - fruit and vegetable consumption: intervention arm significantly more likely to move from not at goal status to goal status compared to control. Physical activity: intervention arm significantly more likely to move from not at goal status to goal status compared to control. Smoking cessation: no significant differences between study arms.</p>	
<p>^Schroy et al. 2011</p> <p>USA</p>	Two urban ambulatory care sites in Boston.	<p>666 participants:</p> <p>397 females,</p> <p>269 male average-risk primary care patients.</p>	<p>2 intervention arms:</p> <p>Computer-based Decision Aid plus</p>	<p>Control arm -</p> <p>Reviewed a discussion of generic lifestyle changes other than screening to</p>	After appointment with physician, which took place immediately	<p>1. Knowledge - no significant differences between the three study arms, but the two study arms together were significantly higher post-test compared to the control arm.</p>	Immediate post-test measures.

			personalised risk assessment OR Computer-based Decision Aid alone.	minimise risk of disease online.	post-intervention.	<p>Mean increase of scores from pre-test to post-test were significantly higher in the two intervention arms compared to the control arm.</p> <p>2. Patient test preferences - overall colonoscopy was the preferred screening method but there were no significant differences overall.</p> <p>3. Satisfaction with the DMP - significantly higher in the two intervention arms compared to the control arm, but the two intervention arms were comparable.</p> <p>4. Screening intentions - significantly higher in the two intervention arms compared to the control arm, but the two intervention arms were comparable.</p> <p>5. Test concordance - the two intervention arms were significantly more likely to have a test ordered compared to the control arm regardless of concordance with the test preferred.</p>	
^Schroy et al. 2012 USA	Two urban ambulatory care sites in Boston.	825 participants: 486 females, 339 male average-risk primary care patients.	2 intervention arms: Computer-based Decision Aid plus personalised risk assessment OR	Control arm - Reviewed a discussion of generic lifestyle changes other than screening to minimise risk of disease online.	1, 3, 6 and 12 months.	<p>1. Test ordering - the DA along arm were significantly more likely to have a test order at 1, 3, 6 and 12 months compared to the control group, and significantly more likely at 1, 6 and 12 months compared to the DA plus personalised risk assessment arm.</p> <p>2. Completion of an actual screening test - no significant differences between the two intervention arms at 6 or 12 months, but the DA</p>	Assignment to the DA alone arm, black race and preference for patient dominant decision making approach were independent predictors of test completion at 12 months.

			Computer-based Decision Aid alone.			alone arm was significantly higher at 6 and 12 months compared to the control arm.	
Steckelberg et al. 2011 Germany	Statutory health insurance scheme	1577 participants, 673 females, 904 males who were members of a target group for colorectal cancer screening.	1 intervention arm: Evidence-based risk information brochure including personalised risk information.	Control arm - received an official information leaflet of the German colorectal cancer screening programme.	6 weeks and 6 months.	<p>1. Actual and planned uptake of screening - no significant differences between study arms at 6 months.</p> <p>2. Informed choice - significantly more likely in the intervention arm at 6 months.</p> <p>3. Knowledge - intervention arm significantly more likely to report 'good' knowledge compared to the control arm at 6 weeks.</p> <p>4. Attitude towards screening - Intervention arm had a significantly less positive attitude about screening at 6 weeks.</p>	<p>No baseline assessment of questionnaires.</p> <p>Planned and actual uptake of screening were assessed together due to the timeframes of CRC screening in Germany.</p>
Vernon et al. 2008 USA	NOT REPORTED	5500 female US Veterans	2 intervention arms: Targeted mail intervention Targeted and tailored mail intervention	Control arm - received the surveys only.	1 and 2 years.	<p>1. Mammography coverage (1 post-intervention mammogram) - no significant differences between study arms in ITT analysis, but for MITT and PP analysis, there was a significant difference between targeted only intervention arm and the control arm.</p> <p>2. Mammography compliance (2 post-intervention mammograms) - women in the both intervention arms were significantly more likely to report receiving 2 post intervention mammograms 6-16 months apart compared to</p>	<p>Intervention based on the TTM.</p> <p>Logistic regression showed that compared with the control arm, the targeted intervention arm had significantly higher mammography coverage and the targeted and tailored intervention arm had significantly higher mammography compliance (PP analysis).</p>

						women in the control arm. There was no evidence of effect modification.	
#Yuksel et al. 2010 Canada	Community pharmacies	262 participants, 169 females, 93 males eligible for bone mineral testing based on national osteoporosis guidelines.	1 intervention arm: Tailored education programme with osteoporosis risk assessment.	Control arm - usual community care plus basic information from Osteoporosis Canada.	4 months	<p>1. Actual screening test (BMD) or new prescription medication for osteoporosis - significantly higher rates in the intervention arm.</p> <p>2. Calcium intake - significantly higher in the intervention arm.</p> <p>3. Vitamin D intake - higher in the intervention arm but not significant.</p>	Primary outcome endpoint was a combination of a screening test or start of osteoporosis medication, although the result was driven by BMD testing.
#Yuksel et al. 2012 Canada	Community pharmacies	262 participants, 169 females, 93 males eligible for bone mineral testing based on national osteoporosis guidelines.	1 intervention arm: Tailored education programme with osteoporosis risk assessment.	Control arm - usual community care plus basic information from Osteoporosis Canada.	4 months	<p>1. Health related QoL</p> <p>2. Physician visits</p> <p>3. Vitamin D Uptake</p> <p>4. Calcium uptake</p> <p>5. Knowledge</p> <p>6. Actual screening test (BMD)</p> <p>Of 129 intervention arm patients, 46% had an abnormal QUS result indicating low bone mass, and 33% of these patients had a follow-up BMD test compared to only 12% of those with a normal QUS result.</p> <p>The strongest predictor of having a follow-up BMD test was, an osteoporosis specific doctors visit.</p>	Other than intervention arm status, those with a follow-up BMD test were significantly more likely to be women, have a family history of osteoporosis or have a higher baseline calcium intake.

						<p>After adjusting for intervention arm status, only female sex and osteoporosis specific physician visit were independently associated with receipt of a BMD test.</p> <p>In the intervention arm, an abnormal QUS result was significantly associated with the receipt of a follow-up BMD test.</p>	
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Significant results indicated in RED.

All of the 18 studies had a control arm, however, 4 of the 18 studies had 2 individualised risk intervention arms, meaning there was a total of 22 individualised risk interventions. Within studies, intervention arms tended to differ in the way the risk was presented to participants or in the additional information presented. Results in this sub-section will be discussed out of a total of 22 intervention arms.

Out of the twenty-two interventions arm in the eighteen studies, seven interventions presented an individualised risk score, seen as the most detailed type of risk to present, such as a score calculated through an algorithm used in the Gail Model for breast cancer risk. Six interventions presented participants with a categorisation of their level of risk such as above average risk, average risk or below average risk. Finally, whilst a further four interventions simply listed or discussed personal risk factors, five interventions were unclear as to the type of risk presented.

The format of the risk presentation also varied largely across intervention arms. Of the 22 intervention arms, two communicated the risk verbally in person only, whilst two interventions communicated the risk verbally in person then additionally provided the risk in written format. One intervention utilised a computer aid to present the risk information, whilst a further three interventions used a computer aid first, followed by a printout, to provide written risk information. Seven interventions provided their participants with written risk information only, two interventions provided written risk information and then reviewed the information verbally in person, two interventions provided written risk information followed by a discussion of this during a telephone call, two interventions communicated the individualised risk through a specialised website, and finally, one intervention communicated risk solely over the telephone.

Interventions where the risk information was presented in person or over the telephone were delivered by a variety of people. Characteristics of those who delivered risk information in this format were largely omitted in terms of the number of people involved, gender, age and ethnicity. "Profession" however was a characteristic reported more commonly in such intervention studies, where the range was wide, from qualified counsellors and nurse educators to health educators and staff specifically recruited and trained for the intervention studies.

All studies provided individualised risk information in conjunction with other information, such as educational material, and the presentation of the individualised objective risk was presented and framed in several ways. Though, the amount of detail that each study provided

their participants with did all vary, therefore studies and their intervention material varied in the complexity. A total of thirteen studies (Allen et al., 2010; Bodurtha et al., 2009; Bowen et al., 2006; Bowen & Powers, 2010; Bowen et al., 2011; Glenn et al., 2011; Harari et al., 2008; Helmes, Culver, & Bowen, 2006; Lipkus & Klein, 2006; Rawl et al., 2012; Schroy et al., 2011; Schroy et al., 2012; Steckelberg, Hulfenhaus, Haastert, & Muhlhauser, 2011; Yuksel, Majumdar, Biggs, & Tsuyuki, 2010; Yuksel, Tsuyuki, & Majumdar, 2012) provided participants with some form of educational material regarding a particular disease or condition or screening test. In two studies (Allen et al., 2010; Schroy et al., 2011; Schroy et al., 2012) the main focus was to aid decision making and a decision aid tool was used, where educational information was provided alongside a decision aid tool to assist in the decision making process about attending for screening. Six studies discussed theoretical constructs alongside the individualised risk information, such as barriers to, and benefits of screening and self-efficacy information (Bloom, Stewart, Chang, & You, 2006; Bodurtha et al., 2009; Glanz et al., 2007; Glenn et al., 2011; Manne et al., 2009; Vernon et al., 2008).. Two studies also provided personalised screening recommendations bases on a persons' level of risk (Glanz et al., 2007; Rawl et al., 2012). Two studies provided follow-up/ check-in calls to their participants (Bowen & Powers, 2010; Glanz et al., 2007), whilst six of the total eighteen studies tailored the additional material to the individual, such as incorrect knowledge about disease or screening test (Bowen et al., 2011; Glenn et al., 2011; Lipkus & Klein, 2006; Manne et al., 2009; Rawl et al., 2012; Vernon et al., 2008). In terms of the actual presentation of the individualised risk information, five studies reported presenting a relative risk (Allen et al., 2010; Bowen & Powers, 2010; Helmes et al., 2006; Lipkus & Klein, 2006; Steckelberg et al., 2011), one study (Steckelberg et al., 2011) presented the risk in natural frequencies, and three studies reported presenting lifetime risk (Bloom et al., 2006; Bodurtha et al., 2009; Bowen & Powers, 2010). Two studies described reporting the individualised risk numerically (Bowen et al., 2011; Helmes et al., 2006), whilst five studies reported presenting the information graphically (Allen et al., 2010; Bowen & Powers, 2010; Bowen et al., 2011; Helmes et al., 2006; Vernon et al., 2008). Finally, one study (two articles) reported using colour-coded categories to present the risk information (Rubinstein et al., 2011; Ruffin et al., 2011).

Seven out of the eighteen studies used theory to inform their interventions. Table 2 shows whether or not there was a theoretical basis to the intervention. The theoretical models addressed were the Health Belief Model (Bloom et al., 2006; Bodurtha et al., 2009; Manne et al., 2009; Rawl et al., 2012; Vernon et al., 2008), Transtheoretical Model (Bodurtha et al., 2009;

Manne et al., 2009; Vernon et al., 2008), Self-Regulatory Theory (Bodurtha et al., 2009; Bowen et al., 2011), Precaution Adoption Process Model (Glanz et al., 2007) , and Dual Process Theory (Manne et al., 2009). One study described having based their intervention on several theoretical concepts (Bowen & Powers, 2010), whilst one other study used their results to support a theory; the Risk Reappraisal Hypothesis (Glenn et al., 2011).

Overall, reporting of intervention details was average to poor. In some interventions, it was unclear how the risk was presented to participants and further details of what participants received were simply not reported in the article (Glenn et al., 2011; Manne et al., 2009; Steckelberg et al., 2011; Vernon et al., 2008).

Table 2- Intervention Details

	Disease / condition being screened for	Individualised risk delivery format	Type of risk presented	Additional details about the intervention	Developed and informed by theory / Theory-based intervention	Significant effect of intervention on outcome
Allen et al. 2010	- Prostate cancer - PSA test	- Interactive computer plus printed report	- Categorisation of risk - Greater than average, / average / less than average	- Relative risk - compared to other men their age. - educational components, prevalence, risk factors, screening methods and recommendations. - On-screen graph	No theoretical model mentioned.	Decisional status knowledge
Bodurtha et al. 2009	- Breast cancer - Mammography	- Computer plus information sheet	- Categorisation of risk - Usual / moderate / strong	- Based on Gail model of risk - Lifetime risk of developing breast cancer - information sheet also described constructs of the HBM, such as barriers to mammography, breast cancer seriousness, benefits of yearly mammograms, self efficacy and cues to action.	- Health Belief Model	-
Bloom et al. 2006	- Breast cancer - Mammogram and Clinical breast exam	- Telephone (by a trained counsellor)	- Individualised risk score - Based on Gail model of risk	- Lifetime risk - Discussed in relation to pre-test perceived risk, de-escalation of tension regarding a breast cancer check up, evaluation of coping skills and information on health protective behaviours and screening guidelines - information on genetic testing if requested.	- Health Belief Model, Self-Regulation Theory and Transtheoretical Model.	Reported physical exercise
Bowen et al. 2006	BRCA gene mutation - BRCA gene testing	1. Individual genetic counselling arm: Verbally in person by a qualified genetic counsellor	- 1. Individualised risk score based on Gail model	- 1. Focus on the genetic background, and educational component of genetic mutation in Jewish population, non-genetic risk factors and screening.	No theoretical model mentioned in the study.	Perceived risk Cancer worry Awareness of genetic testing

		2. Group psychosocial counselling: Written - session led by qualified health counsellor	- 2. Individualised risk score based on Gail model	- 2. Educational component, stress management and problem solving, and social support		Interest in genetic testing Candidacy for genetic testing
Bowen et al. 2010	- Breast cancer - Mammography	Written - personalised risk sheet within personalised booklet - Those at mixed risk or genetic risk received the written report in person by a counsellor.	- Individualised risk score based on Gail model	- Lifetime risk presented in a bar graph, with an average woman's risk estimate also presented. - Intervention pack included personal risk sheet, screening information, BSE shower card, Cancer Institute flyer. - Check in call to discuss personal risk and worry - Counselling offered to those at mixed or genetic risk.	- Based on theoretical concepts - perceived risk, potential distress at learning about personal risk and coping with breast cancer risk by performing screening.	Mammography uptake Quality of life Monthly BSE Interest in genetic testing
Bowen et al. 2011	- Breast cancer - Mammography	Website - personal risk sheet - Those at mixed risk or genetic risk received the written report in person by a counsellor.	- Individualised risk score based on Gail model	- lifetime risk estimate presented both numerically and graphically, - percentage - bar graph of a women's estimated risk of developing breast cancer. - Tips, personal stories, facts tailored to risk level and health news.	- Self-Regulation Model	Knowledge of genetic testing Mammography screening Knowledge of breast cancer Quality of life Breast self-examination Cancer worry
Glanz et al. 2007	- Colorectal cancer	- Verbally in person and written in a counselling session	- Categorisation of risk - Risk level 1, 2 or 3.	- follow up phone call	- Precaution Adoption Process Model	Screening adherence

	- FOBT / Colonoscopy / Sigmoidoscopy	by a nurse educator or trained health educator.		- feedback about perceived barriers and benefits to screening, personal screening recommendation according to risk category, action planning form.		Risk comprehension Knowledge Health behaviours
Glenn et al. 2011	Colorectal cancer	- Written in tailored booklet - Telephone reminder if necessary at 6 months.	UNCLEAR - 6-month telephone call - discussion of personal risk factors if participant still unscreened.	- Educational components - information on colorectal cancer, risk factors and screening - Tailored inserts - motivational statements tailored to readiness to screen and listed barriers to screening.	No theoretical model mentioned in the development of the intervention but Risk Reappraisal Hypothesis applied to evaluate results.	Screening receipt Perceived risk
Harahi et al. 2008	- Mixed	- Written in an individualised report	- Discussion of personal risk factors with personalised preventative health checklist.	- Feedback included advice on modifying health risks.	- No theoretical model mentioned in the study.	Health risk behaviours Preventative care measures
Helmes et al. 2006	- Breast cancer / BRCA gene mutation - Genetic testing / Mammogram	- Intervention arm 1. In-person risk counselling: Verbally in person plus mailed risk sheet. - Intervention arm 2. Telephone risk counselling: Mailed risk sheet and over telephone.	- Individualised risk score - Based on Gail model - Individualised risk score - Based on Gail model	- presented both graphically and numerically, and compared with the personal risk of an average-risk woman and a high-risk woman. - Conducted by a board certified genetic counsellor. - booklet also contained educational information and discussion of genetic testing.	- No theoretical model mentioned in the study.	Cancer worry Risk perceptions Interest in genetic testing
Lipkus et al. 2006	- Colorectal cancer - FOBT	- Intervention arm 1. Absolute risk: written information	- Absolute risk; list of personal risk factors that may increase chances of developing CRC.	- Booklet - contained educational materials - Plus tailored messages about lifestyle risk factors	- No theoretical model mentioned in the study.	Barriers to screening

		<p>first then reviewed verbally in person.</p> <p>Intervention arm 2: Absolute plus comparative risk: written information first then reviewed verbally in person.</p>	<p>- Absolute risk; list of personal risk factors that may increase chances of developing CRC plus comparative risk - more or less risk factors compared to others.</p>	<p>- Reviewed after reading the written information by the research assistant who emphasised the risk factors relevant to each individual (as well as how those risk factors compared with others for the absolute and comparative risk group only).</p>		<p>Perceptions of comparative risk</p> <p>Attitudinal ambivalence</p> <p>Screening Intentions</p>
Manne et al. 2009	<p>- Colorectal cancer</p> <p>- Colonoscopy</p>	<p>- Intervention arm 1. Tailored print: Written in tailored pamphlet</p> <p>- Intervention arm 2. Tailored print and telephone counselling: Written in tailored pamphlet</p>	<p>- UNCLEAR</p> <p>- UNCLEAR</p>	<p>Booklet contained:</p> <ul style="list-style-type: none"> - Picture of a gender and ethnically matched individual with a caption discussing the participants highest ranking barrier - tailored to incorrect CRC knowledge, benefits and barriers, stage of adoption and commitment to screening. - Telephone counselling by health educators. Used motivational interviewing to motivate readiness to have screening, discuss benefits, correct knowledge. - Tailored newsletter 1 month after tailored pamphlet reviewed stage of adoption, reinforce facts and present alternative views of barriers. 	<p>-Transtheoretical Model</p> <p>- Health Belief Model</p> <p>- Dual Process Theory</p>	<p>Screening adherence</p> <p>Decisional balance</p>
Rawl et al. 2012	<p>- Colorectal cancer</p> <p>- Mixed</p>	<p>- Presented on a portable computer plus printout</p>	<p>- Discussion of personal risk factors</p>	<ul style="list-style-type: none"> - personalised recommendations for screening presented also. - delivered messages, graphics and videos tailored on the assessment of their perceived risk, family history, age, barriers to screening. - Educational component through animation and narration. - Coloured printout imported visuals and data from computer summarising personal risk factors and risk appropriate test recommendations. 	<p>- Health Belief Model</p>	<p>CRC knowledge</p> <p>Perceived Risk</p> <p>Perceived barriers to FOBT</p> <p>Perceived benefits of Colonoscopy</p>

Rubinstein et al. 2011 / Ruffin et al. 2011	- Mixed - Mixed	- Presented on a website - over the telephone in 9% of participants - printed prevention messages	- Categorisation of risk - Strong / moderate / weak	- qualitative framing - colour-coded categories (strong displayed in red) - Tailored prevention messages based on familial risk level, sex, age, reported health behaviours and screening history.	- No theoretical model mentioned in the study.	Behaviour change
Schroy et al. 2011 / Schroy et al. 2012	- Colorectal cancer - Mixed	- Portable DVD-formatted computer decision aid with risk assessment and feedback.	- Categorisation of risk - Above average / average / below average	- suggestions for behaviour modification - DA consisted of educational information about CRC and screening tests with audio and visual comparisons, decision making tool to identify a screening preference	- No theoretical model mentioned in the study.	Knowledge Satisfaction with the DMP Screening intentions Test concordance Test ordering
Steckelberg et al. 2011	- Colorectal cancer - FOBT and Colonoscopy	- Written evidence based risk information brochure.	UNCLEAR	- 38-page brochure covering personalised risk of CRC, all available screening options with possible benefits and harms, and prevention of CRC. - Access to two interactive internet modules offering the opportunity to read more on the topic. - Natural frequencies with comparable reference populations and timeframes.	- No theoretical model mentioned in the study.	Knowledge Informed choice
Vernon et al. 2008	- Breast cancer -Mammography	Written letter with tailored risk assessment and feedback.	UNCLEAR	- graphical illustrations of objective risk and perceived risk for breast cancer - messages designed to help reconcile perceptions with actual risk	- Transtheoretical Model - Health Belief Model	Mammography coverage Mammography compliance

				- feedback on self-efficacy to get a mammogram and strategies to increase confidence to overcome identified barriers, review use of processes of change and list of activities tailored to stage of change, and reminder of date of next due mammogram.		
Yuksel et al. 2010 / Yuksel et al. 2012	Osteoporosis	Verbally in person by a community pharmacist	- Categorisation of risk based on QUS measure. - Unclear	- Tailored education programme on aspects of osteoporosis such as risk factors, BMD testing, lifestyle measures, calcium and vitamin D intake, and medications. - QUS measure - to aid risk assessment - encouragement to follow-up with their doctor for further management.	- No theoretical model mentioned in the study.	Actual screening test

Key

HBM - Health Belief Model

TTM - Transtheoretical Model

CRC - Colorectal cancer

FOBT - Fecal Occult Blood Test

BMD – Bone Mineral Density

DA - Decision aid

DMP - Decision making process

ITT - Intention-to-Treat analysis

MITT - Modified Intention-to-Treat analysis

PP - Per-protocol analysis

QoL – Quality of life

*Same data, two articles reporting two different outcomes.

^Same study, the first of which reports results of the first 666 participants enrolled in study, and the second reports results of different outcomes of all 825 participants enrolled.

#Same study, first article reports the primary analysis and the second article reports on a secondary analysis.

KEY:

Type of Risk presented:

Categorisation of risk

Individualised risk score

Discussion of personal risk factors

Individualised risk delivery format:

Verbally in person

Written

Website

Computer plus printout

Telephone

Verbally in person then written

Computer only

Written then verbally in person

Written plus telephone

Outcomes Measured:

All 21 studies took baseline measures and follow-up measures post intervention, although timing varied among studies. Table 1 shows the outcome measures for each study. There was a lot of variation in the outcomes measured. No two studies measured the exact same outcomes. In terms of a primary outcome, eleven of the eighteen studies measured actual screening uptake, while four studies measured screening intentions, and one study measured actual combined with planned screening uptake. Secondary outcomes varied even more so. Perceived risk was measured in eight studies, while other common outcome measures included knowledge; reported in nine studies, and cancer worry, measured in eight of the studies. Beyond these, there was a range of outcomes for which only one or two studies provided data such as for perceived severity and quality of life.

Risk of Bias:

Data was extracted to assess the risk of bias of the included studies using Cochrane's risk of bias tool derived from the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2011). Differences were resolved in assessment of the risk of bias included studies by discussion. The principal elements used for this review were:

- Random sequence generation (selection bias): Studies that describe the random sequence generation were marked as low risk. If there was no mention of this, then the studies were marked as unclear. Quasi-randomised trials were marked as high risk.
- Allocation concealment (selection bias): Studies that describe allocation concealment were marked as low risk. If there was no mention of this, then the studies were marked as unclear. Studies were marked as high risk if an allocation concealment procedure was clearly not followed.
- Blinding of participants and personnel (performance bias): Studies that describe blinding in detail were marked as low risk. If there was no mention of this, then the studies were marked as unclear. Studies were marked as high risk if a blinding procedure was clearly not followed or the trialists described the participants and personnel in the study as unblinded.
- Blinding of outcome assessment (detection bias): Studies that describe blinding in detail were marked as low risk. If there was no mention of this, then the studies were marked as unclear. Studies were marked as high risk if a blinding procedure was clearly not followed or the researchers described the outcome assessment procedure as unblinded.

- Incomplete outcome data (attrition bias): Studies were marked as low risk if there was a low attrition rate (less than 20%) or if an intention-to-treat principle was adopted. If there was no description of attrition in the study, this element was marked as unclear. If no adjustments were made despite a significant dropout rate studies were marked as high risk for attrition bias.
- Selective reporting (reporting bias): Studies were marked as low risk if the protocols were available and all outcomes listed in it were addressed. They were marked as unclear if protocols were not available. High risk status was assigned if there was clear evidence of selective reporting based on the outcomes mentioned in the methods section of the included studies.
- Other biases, e.g. baseline comparability, measure against contamination and funding for the screening test: Studies that describe the components in detail were marked as low risk. If there was no mention of this, then the studies were marked as unclear. Studies were marked as high risk if the components were clearly not addressed, or demonstrated biases.

This review found that the included studies were of variable quality, but generally average to good. The majority of studies were adequate for random sequence generation, but only some of the studies reported adequate concealment of allocation to intervention or control groups. Most studies were also unclear about the blinding of assessors in outcome measures although many used patient-reported or objective measures for key outcomes such as assessing test uptake from computerised registers. There was adequate incomplete outcome data across studies. Finally, there appeared to be some selective reporting across studies, however, there were no major concerns about the risk of bias, therefore no studies were excluded on the basis of the risk of bias.

Results of Individual Studies:

Most (N=14/18) studies reported some degree of positive findings; IRC-based interventions had a significant effect on screening uptake (N=2), its psychological predictors (N=6), or both (N=6). One study found no effects on either outcome (Bloom et al., 2006), whilst N=3 found no effect on either screening uptake or its psychological predictors but saw a significant increase in related health behaviours such as fruit and vegetable consumption (Rubinstein et al., 2011; Ruffin et al., 2011), exercise (Bodurtha et al., 2009; Harari et al., 2008; Rubinstein et al., 2011; Ruffin et al., 2011) and vaccination uptake (Harari et al., 2008).

Table 1 presents details of the main findings reported for each of the 18 studies in 21 articles.

It would appear that in some of interventions, the use of tailored risk based information had some effect on participants' screening behaviours or psychological predictors of screening uptake compared to generalised risk information or a control arm.

Conceptually, a meta-analysis uses a statistical approach to combine the results from multiple studies in an effort to increase power (over individual studies), improve estimates of the size of the effect and/or to resolve uncertainty when reports disagree. There was insufficient homogeneity among the interventions in either the risk presentation types, formats and methods adopted or the outcome measures used to undertake a meta-analysis of the trials, thus it is not possible to provide a clear overall statement of the impact of the interventions. In order to conduct a meta-analysis, more than one study which has estimated the effect of an intervention or of a risk factor is needed. The participants, interventions or risk factors, and settings in which the studies were carried out need to be sufficiently similar in order to say that there is something in common to be investigated.

Screening uptake was significantly higher in the intervention arms compared to control arms in seven of the studies, and one or more studies also reported other significant intervention effects such as higher screening intentions, greater or more accurate risk perceptions, lower levels of cancer worry, greater knowledge, higher decisional status, greater informed choice and reduced interest in genetic testing. Therefore, it appears that individualised risk communication may have a positive impact on screening uptake and factors that can mediate the decision to attend for screening.

Type of risk presented:

It is possible that studies using an individualised risk score or categorising risk may be more successful at increasing uptake of screening tests compared to simply listing personal risk factors. However, this conclusion is made with caution as some studies reporting an increase in screening uptake were unclear about the type of risk presented i.e. risk category or individualised risk score, or this detail was simply not reported.

Five studies (seven intervention arms) presented participants with an individualised score. Of these five studies, two studies (Bowen et al. 2010; Bowen et al. 2011) reported an increase in

screening uptake, and three studies (Bowen et al. 2010; Bowen et al. 2011; Helmes et al. 2006) reported better psychological outcomes such as cancer worry and quality of life.

Six studies presented participants with a categorisation of their individual risk. Of these six studies, two studies uptake (Glanz et al. 2011; Yuksel et al. 2010/Yuksel et al. 2012) reported an increase of screening uptake, whilst three studies (Allen et al. 2010; Glanz et al. 2011; Schroy et al. 2011/Schroy et al. 2012) reported better psychological outcomes such as knowledge.

Three studies (four intervention arms) presented participants with a list of personal risk factors. Of these three studies, there was no report of any increase in screening uptake, whilst two studies reported better psychological outcomes such as fewer barriers to screening (Lipkus & Klein, 2006; Rawl et al. 2012). There were no studies which had two intervention arms where different types of risk were presented and compared.

Disease or condition and Screening test:

The most common disease being screened for was colorectal cancer, followed by breast cancer. Results from the studies did not indicate more favourable outcomes for any particular disease or condition. Interventions successfully increased screening uptake in a variety of diseases. However, it appears that the two interventions providing individualised risk information about a number and variety of diseases or conditions were less successful at having an effect on screening uptake of particular diseases or conditions compared to interventions which only focused on one particular disease or condition such as breast cancer. There were insufficient data to report on other psychological outcomes at this level of synthesis.

Type of participants:

Seven studies recruited a participant sample thought to be at greater risk of developing a particular disease or condition due to their family history or non-adherence to screening, for example. Of these seven studies, three reported an increase in screening uptake with individualised risk (Glanz et al. 2011; Glenn et al. 2011; Manne et al. 2009), whilst six reported improved psychological outcomes (Bowen et al. 2006; Glanz et al. 2011; Glanz et al. 2011; Lipkus & Klein, 2006; Manne et al. 2009; Rawl et al. 2012). Eleven studies recruited average risk participants from the general population. Of these, 4 studies reported an increase in

screening uptake with individualised risk (Bowen et al. 2010; Bowen et al. 2011; Vernon et al. 2008; Yuksel et al. 2010/Yuksel et al. 2012), whilst six of the studies reported improved psychological outcomes (Bowen et al. 2010; Bowen et al. 2011; Helmes et al. 2006; Schroy et al. 2011/Schroy et al. 2012; Steckelberg et al. 2011). Therefore, these studies did not seem to suggest any greater increase of screening uptake utilising a sample of participants at greater risk for a disease or condition over studies utilising an average risk participant sample. However, there was heterogeneity between the studies in the way the risk was presented, and the outcomes measured, adding to the difficulty in providing a definitive conclusion.

Risk information delivery format:

Although there were a variety of formats in which the risk was presented, there does seem to be more support some risk information formats than others. Seven intervention arms presented risk information in a written format, of which four of the interventions reported an increase in screening uptake (Bowen et al. 2010, Glenn et al. 2011; Manne et al. 2009; Vernon et al. 2008), and five interventions reported improved psychological outcomes (Bowen et al. 2006; Bowen et al. 2010; Glenn et al. 2011; Manne et al. 2009; Steckelberg et al. 2011). Two intervention arms provided written risk information first, followed by a discussion of the risk verbally in person, but did not increase screening uptake, although they did report better psychological outcomes (Lipkus and Klein, 2006). One study reported presenting the individualised risk information on a computer aid alone which did improve several psychological outcomes such as knowledge and screening intention, but screening uptake did not increase (Schroy et al. 2011/Schroy et al. 2012). A further three interventions used a computer aid first, followed by a printout, to provide written risk information, which resulted in no increase in screening uptake, yet two of the interventions reported better psychological outcomes (Allen et al. 2010; Rawl et al. 2012). Two intervention arms communicated the risk verbally in person only and whilst one intervention (Yuksel et al. 2010/Yuksel et al. 2012) reported an increase in screening, the other reported better psychological outcomes (Bowen et al. 2006). For the two interventions communicated the risk verbally in person then additionally provided the risk in written format (Glanz et al. 2011; Helmes et al. 2006), both studies reported better psychological outcomes, whilst one intervention reported an increase in screening uptake also (Glanz et al. 2011). Two interventions provided written risk information followed by a discussion of this during a telephone call. Both interventions reported better psychological outcomes (Helmes et al. 2006; Manne et al. 2009), and one intervention reported an increase in screening uptake (Manne et

al. 2009). Two interventions communicated the individualised risk through a specialised website, and whilst one intervention reported no increase in outcomes (Rubinstein et al. 2011/Ruffin et al. 2011), the other reported both an increase in screening uptake and improved psychological outcomes (Bowen et al. 2011). Finally, one intervention communicated risk solely over the telephone (Bodurtha et al. 2009), but this intervention reported no increase in screening uptake or any psychological outcomes.

Overall, all individualised risk information formats utilised within the 22 intervention arms, except that of risk communication solely over the telephone, had a significant effect on psychological outcomes. It appears though, that where individualised risk information is presented in written format, or indeed in a combination with another format such as communication verbally in person or over the telephone, it appears to have an increase in screening uptake also.

Details of risk presentation:

Thirteen of the eighteen studies provided educational information for participants, and all except two studies (Bodurtha et al. 2009; Harahi et al. 2008) reported some effect of better outcomes compared to the control arm. There appear to be similar findings with the addition of several other components to the interventions. Both interventions using a decision aid reported better psychological outcomes compared to the control arm, and the six studies which discussed theoretical model constructs with participants all reported increased screening uptake or psychological outcomes. The two studies using a check in follow-up call as part of the intervention also both reported increases in screening uptake and better psychological outcomes (Bowen et al. 2010; Glanz et al. 2011), and finally, those studies tailoring the intervention to individuals as well as presenting individualised risk information all reported some level of better outcomes either increased screening uptake or better psychological outcomes (Bowen et al. 2011; Glenn et al. 2011; Lipkus & Klein, 2006; Manne et al. 2009; Rawl et al. 2012; Vernon et al. 2008).

The same can be said for other details of risk presentation reported in the studies, such as presenting a relative risk, where all five studies reported positive effects on screening or psychological outcomes, lifetime risk, where one study reported positive screening uptake and

better psychological outcomes, and where one study reported natural frequencies, and found positive effects on psychological outcomes.

Therefore, it is difficult to conclude which intervention strategy results in the best overall outcome for increasing screening uptake, and which is the best way to visually present the risk information, as there is very little by way intervention presentation that is not effective.

Simple versus complex Individualised risk interventions:

Four of the eighteen studies each compared two intervention arms both receiving individualised risk information, with a control arm (Bowen et al. 2006; Helmes et al. 2006; Lipkus & Klein, 2006; Manne et al. 2009). The two interventions in each of the four studies varied in their complexity. In one study, both intervention arms received the same individualised risk information but in different settings; one arm received their written risk information with one-to-one non-directive counselling, whereas the other group received it with group psychosocial counselling. Results showed there to be no significant differences between either counselling method in the overall increase of screening uptake that both arms showed compared to the control group.

In one of the other studies both intervention arms received the written individualised risk information, but whilst one intervention arm received theirs during in-person counselling, the other intervention arm was mailed the intervention packet containing the individualised risk information, and received telephone counselling (Helmes et al. 2006). However, results showed that there was no difference in psychological outcomes between the two intervention arms, although both had better outcomes compared to the control arm.

In another study (Lipkus & Klein, 2006), both interventions arms received individualised absolute risk information, but one of the arms was more complex and received more relative risk information also. Here, results showed that although the more complex intervention increased screening intentions compared to the simpler intervention arm, but there was no difference in actual screening uptake between the two intervention arms.

Finally, in the other study, both intervention arms received individualised risk information in tailored print, however, one of the intervention arms also received telephone counselling, the

more complex intervention of the two arms (Manne et al. 2009). Again, results showed that both intervention arms increased screening uptake compared to the control arm.

Therefore, it seems that, more complex interventions do not seem to have an additive effect on overall outcomes. They appear to be just as effective as the simpler individualised risk interventions.

Interventions with a theoretical basis:

Seven studies (Bloom et al., 2006; Bodurtha et al., 2009; Bowen et al., 2011; Glanz et al., 2007; Manne et al., 2009; Rawl et al., 2012; Vernon et al., 2008) used theoretical models to inform the development of their intervention, one study used several psychological concepts (Bowen & Powers, 2010), whilst ten did not. These ten studies, measured outcomes related to behaviour-change psychology theory such as knowledge, perceived risk, and worry.

There did not appear to be any significant differences in the success of interventions to increase screening uptake or better psychological outcomes, between those that were informed using a theoretical model, and those that were not. For example, increases in knowledge, perceived risk and screening uptake and reductions in cancer worry and interest in genetic testing, were seen in both studies that used theory to inform their intervention, and studies that did not.

Overall, there was a higher level of risk information presentation detail omitted in the studies which lends to the difficulty in concluding the most effective individualised risk communication strategy.

Discussion:

Summary of Evidence:

Notwithstanding the moderate quality of reviewed studies, and the heterogeneity in outcomes, there does seem to be support for a wide range of individualised risk communication strategies.

Following a systematic review of 21 articles, there does appear to be evidence that individualised risk communication is more successful than generalised risk communication at increasing screening uptake and its psychological predictors. There is also limited evidence to

suggest that more detailed types of risk presented, such as an individualised risk score or a risk category, are slightly more successful at increasing screening uptake and its psychological predictors compared to simply listing personal risk factors. However, there were interventions that were successful at increasing screening uptake and its psychological outcomes that did not report on the type of risk presented so this result is to be taken with caution (Manne et al., 2009; Steckelberg et al., 2011; Vernon et al., 2008).

The results also suggest that interventions may not be any more successful for participants identified at greater risk for a particular disease or condition, rather than average-risk individuals, even though in this current review, there were a number ($n=7$) of studies recruiting participants thought to be at greater risk.

Interventions that provide individualised risk about a number of conditions may not be as successful as those which focus on a particular disease or condition, providing further support for the findings from a previous systematic review (Edwards et al., 2006). This might be because individuals cannot take in risk information about several conditions and process the information properly in order to make a screening decision about every disease. As Kahneman's theory of attention and effort suggests, attention can either be focussed on one particular activity or divided between a number of activities (Kahneman, 1973). Attention is limited, and therefore, the more activities, the less attention is paid to each individual activity. Where the risk of just one disease is presented, individuals are more likely to be able to focus and process the information in order to make a decision about attending for screening.

There also seems to be support for the presentation of the risk information in a written format, or in a combination with another presentation format such as verbally in person. This may be because participants preferred to have the information to hand to review again, or to take in at their own pace.

Complex interventions which involve other components such as counselling and educational information about a particular disease or condition or methods of screening, presented in addition to the risk information, although successful in terms of screening and psychological outcomes, appear to be no more successful than more simple interventions which do not utilise such components in the intervention.

Psychology theory has been used in designing IRC interventions to increase screening uptake or its psychological proxies and such studies are as effective in improving screening or its psychological proxies, as a-theoretical studies. There seems to be no evidence to suggest that using theory to inform intervention development is more likely to increase screening uptake, nor does the use of any particular visual presentation detail such as numerical or graphical risk representations appear to be more successful at affecting psychological predictors of screening uptake and actual screening uptake. This could be because theory is truly unhelpful in predicting outcomes, or because intervention fidelity was poor in the reported interventions, or possibly because of improper use of behaviour change techniques. Interestingly, all of the atheoretical studies measured outcomes that are supported by theory (such as e.g. attitudes) albeit the absence of theory to actually drive the design of the intervention per se.

This systematic review compliments and builds on the findings from Edwards and colleagues in many ways. Firstly, they reported that only a limited number of clinical topics were targeted in risk communication work, namely breast cancer. Since their review, there have been a few other clinical topic areas examined, such as prostate cancer and osteoporosis and mixed clinical topic conditions, where studies have examined risk of developing several diseases or conditions together. Secondly, he found that a lot of interventions used the most basic form of individualised risk communication, where there was simply a discussion of personal risk factors. He reported fewer cases of categorising risk or using an individualised risk score, whilst at the same time reporting that the more detailed the risk i.e. using an individualised risk score to be smaller the effect on increasing screening uptake. Studies published since their review findings appear to have communicated individualised risk in more detailed ways, and this current review found there to be more individualised risk scores and categories of risk being utilised rather than simply listing personal risk factors. This observation suggests that this area of research has changed and taken note of the previous findings.

The findings in the current review support those previously reported in a recent selection of RCTs, in that individualised risk communication seems to be more effective in increasing screening uptake than generalised risk communication or no communication. In addition to supporting the findings of Edwards and colleagues, the current review suggests that individualised risk communication can significantly impact the psychological predictors of screening uptake. It also proposes that presenting the individualised risk in a written format or in deed in a combination with another format such as verbally in person, that this may be more

effective that other methods of delivery such as communicating the risk solely over the telephone or viewing the risk on a website.

The current review also builds on the findings from the systematic review conducted by Waldron et al. (2011). They made recommendations for more studies to assess a person's actual risk profile rather than carry out analogue studies, and although their focus was communicating individualised cardiovascular risk, their recommendations appear to have been noted, as in this review, there were no analogue studies found in the search of studies for inclusion. The findings of this review also support their results; they found that presenting patients with their cardiovascular risk in percentages or frequencies; numerically, using graphical representation and short timeframes was best for achieving risk reduction through behaviour change. Indeed, this review found that studies utilising graphical or numerical representations of risk were successful at increasing screening uptake or resulting in better psychological outcomes, although neither were found to be superior due to lack of reporting in many studies at this level of detail, and the heterogeneity of studies and outcomes. On the other hand, they suggested that numerical presentation of risk as opposed to simple risk categories might lead to more accurate risk perceptions and can influence treatment decisions (Waldron et al., 2011). Conversely, this current review suggests that categories of risk are not necessarily superior, as previously suggested (Waldron et al., 2011), to numerical presentation; in this review we call individualised scores, but might be equally as effective at influencing screening decisions, and both better than simply listing personal risk factors. However, this conclusion is made with caution, as some studies were unclear as to the type of risk presented.

Quality of the Studies:

It is important to consider the conclusions made in this review in light of critical analysis of the study quality. Overall, individualised risk communication interventions were poorly reported, and the presentation detail was not described in order to answer the review question and identify a full effective strategy for communicating individualised risk information.

Further to this, there were several problems noted for studies included overall. Firstly, not all studies measured screening uptake, but those studies that did were largely based upon self-reported receipt of a screening test. Within studies measuring screening uptake, only a few studies confirmed receipt of a screening test by consulting physicians or medical records.

Secondly, follow up times varied massively between studies from immediately post-intervention up to two years. A lack of an appropriate post-test measure can reduce clarity of conclusions, and that it is useful to have longer term measures, to see whether the impact of the intervention does stay with the participant. This is especially important when assessing follow-up screening uptake as many screening tests are only carried out annually or even every two or three years, meaning that shorter follow-up times might not be sensitive enough to detect changes in screening adherence.

Conversely, all scales and measures used in the studies were validated and checked for reliability and validity, which increases the confidence we can place in the results obtained. Additionally, all 18 of the studies were RCTs, and had an adequate control group.

Limitations:

The conclusions of this review are based on a relatively small number of studies. This is, even though it had been several years since the topic was last systematically reviewed. Albeit a few additions, the variety of clinical topics is still quite narrow, with the majority of studies producing results in the field of colorectal cancer and breast cancer. Additionally, there is a possible selection bias in the current review with the exclusion of papers pre-2006 and of non-English language studies. Papers that were published pre-2006 were excluded because it was decided that papers up to this point were included in a previously published systematic review and the findings of these had been evaluated adequately by the author. Further to this, there were several problems noted for studies included overall. Firstly, not all studies measured screening uptake, but those studies that did were largely based upon self-reported receipt of a screening test. Within studies measuring screening uptake, only a few studies confirmed receipt of a screening test by consulting physicians or medical records. Secondly, follow up times varied massively between studies from immediately post-intervention up to two years. A lack of an appropriate post-test measure can reduce clarity of conclusions; therefore, it is useful to have longer term measures, to see whether the impact of the intervention does stay with the participant. This is especially important when assessing follow-up screening uptake as many screening tests are only carried out annually or even every two or three years, meaning that shorter follow-up times might not be sensitive enough to detect changes in screening adherence. Whilst the risk of bias tool was used to assess the quality of the studies included in

the review, a full quality assessment of the studies to assess the strength of the evidence could have been conducted using CASP checklists for instance (CASP, 2014).

However, the strength of the results lies in the fact that the studies have been gathered from systematic searches of several key databases and contact with key authors in the field, and represent a narrative synthesis of the most recent literature.

Implications for Healthcare Settings:

There is a need simple risk calculators to be incorporated into healthcare in order to deliver risk information to individuals. The Gail model and methods for calculating cardiovascular risk such as the UKPDS Risk Engine for diabetes patients are examples of those currently developed, but only the latter has been incorporated into routine clinical practice. Models that allow calculation of individualised risk estimates for individuals about other conditions, such as cervical or prostate cancer are needed so that further evaluation of the effects of providing such individualised risk information to consumers can be explored. Further, it is important to encourage informed decision making rather than just focussing on increasing screening rates to meet policy requirements, as some studies have shown a decrease in interest in screening tests post-risk communication intervention.

There are of course cost implications to any intervention. What is promising is that the more complex interventions (which presumably, by their very nature, are more costly) do not appear to be any more effective than simpler interventions. However, it would be useful to formally assess the cost-effectiveness of the reviewed interventions in order to inform the feasibility of implementation of integrating IRC into screening programs. Insufficient information is provided in the existing studies to perform such an evaluation. Future risk communication intervention studies should aim to include this information so that the cost effectiveness of the intervention can be assessed.

Conclusion:

This review demonstrates a lack of well-reported studies in individualised risk communication. This has been due to a combination of diverse methodological quality and contradictory results. It is likely that the heterogeneity of study characteristics, such as the design, sample and types of individualised risk presented have contributed to this. A wide range of outcomes have been

measured too, and there has been little consistency in risk presentation. Therefore, there is a need for more individualised risk communication interventions in more diverse clinical topics. RCTs comparing different risk presentation formats are needed to examine whether peoples' intentions, perceptions and other psychological screening predictors vary by risk presentation and format as these are possibly more responsive to change. There is a lack of well-reported studies which report the full intervention details so that methods of presentation can be completely evaluated.

August 2015 Update:

The systematic review reported above was conducted in 2012. Due to the objective of this systematic review to inform the next chapter of the thesis, it was deemed unnecessary to fully update the review for thesis submission as the findings of the review were already followed to design the next part of the project. However, for the purposes of good practice, the search strategies used originally were re-run to see what research had been conducted since. Six additional studies were deemed eligible based on the original inclusion criteria set.

On examination of the six additional papers, very little has changed from previous studies included in the review in that the majority of studies reported some degree of positive findings; that individualised risk communication-based interventions had a significant effect on participants' screening uptake and/or its psychological predictors.

Overall, there were 3274 participants in the six additional studies, ranging in age, level of risk of disease and gender. Diseases that were examined included colorectal/bowel cancer, skin cancer, prostate cancer and coronary heart disease (CHD). CHD and skin cancer did not appear in the papers originally included in the review so these are new developments in the field suggesting that risk communication is now being investigated in a greater number of diseases. Several theoretical concepts featured in the recent papers and were measured similarly to previous studies. The outcomes measured were also very similar to those measured in the original papers. Where actual screening uptake was not measured, screening predictors were. Length of follow up varied again, ranging from 2 weeks to 12 months. As with the original papers included in the review, risk delivery format varied from written to web based formats and numerical to categorical representations of personalised risk. The

majority of personalised risk interventions were complex and featured several components alongside a participants personalised risk information.

The quality of the studies was average to good, as assessed by the Cochrane's risk of bias tool. After close inspection of the six latest papers that were found using the original search strategy, it was decided that these papers did not add anything new to the conclusions reached from the original papers.

Colorectal cancer still features heavily in the literature, however, skin cancer and CHD were new diseases being screened for in these studies and did not feature in the original set of studies. In summary, although the quality of these RCTs was average when considering Cochrane's ROB assessment, there is still a lack of detail about the interventions and how personalised risk is presented in order to fully evaluate these.

Chapter conclusion

This chapter has presented the findings of a systematic review on how best to communicate risk in order to increase screening participation. On the basis of these findings, it was decided that a simple intervention be conducted where dental patients receive individualised diabetes risk information in the form of a risk score with a corresponding risk category, both verbally in person, and in writing. The use of this systematic review informed communication intervention is described in detail in chapter four.

Chapter 4

Methods

Background

The rest of this thesis reports on one major study with various components. The work described here aimed to screen dental patients for diabetes, using two different screening tests. It also examined whether post-screening, participants followed up the advice to attend their GP for formal diagnostic testing where necessary. The psychological profile of attenders and non-attenders was also explored seeking to identify psychological predictors of diagnostic testing. This aspect of the thesis relied on the use of quantitative methods. Additionally, the thesis reports on qualitative studies undertaken with patients who either attended or did not attend for diagnostic testing after screening, and with the dentists who participated in this programme of research.

This project set out to incorporate the use of both quantitative and qualitative methods to answer the research questions outlined in chapter one. The project involved collecting qualitative data after a quantitative phase in order to explain and follow up on the quantitative data in more depth. Health care research published in the last decade has included many studies that combine quantitative and qualitative methods (Sale, Lohfeld, & Brazil, 2002). Mixed methods research is defined as the class of research where the researcher mixes or combines quantitative and qualitative research techniques, methods, approaches, concepts or language into a single study (Johnson & Onwuegbuzie, 2004). Combining qualitative and quantitative methods in a single study is widely practiced and accepted in many areas of health care research (Sale et al., 2002). By using a mixed method design, the researcher was able to address several questions and meant that any limitations of using a single design were overcome. The goal of mixed methods research is not to replace either of these approaches but rather to draw from the strengths and minimise the weaknesses of both quantitative and qualitative methods in single research studies and across studies. Mixed methods research offers great potential for practicing researchers who would like to see methodologists describe and develop techniques that are closer to what researchers actually use in practice. Mixed methods research can also help bridge the division between quantitative and qualitative research (Johnson & Onwuegbuzie, 2004).

The impact of using a self-report screening measure and HbA1c information as preliminary screening tools for possible diabetes in general dental practice, on patients' health behaviours was investigated in a non-experimental design. The primary outcome of the study was uptake of further diabetes diagnostic testing by the patients GP. A secondary outcome of the study was the amount of variance that psychological variables can predict uptake of further diagnostic testing following the receipt of a positive result on the FINDRISC and/or a high HbA1c reading.

In particular, the research questions in bold were addressed.

1. What is the most effective way to communicate individualised risk information to increase screening participation or its psychological predictors?
2. **What proportion of dental patients accept an offer to be screened for type 2 diabetes in a primary care dental setting?**
3. **What is the risk of type 2 diabetes in primary care dental patients as assessed through self-report and physiological measures?**
4. **What is the effect of personalised diabetes risk communication on subsequent health behaviours?**
5. **What is the psychological profile of patients at risk of diabetes?**
6. **To what extent do psychological variables predict post-screening further testing or health behaviours?**
7. **What are patients' and dentists' views on screening for diabetes in dental settings, and can this help to further explain post-screening further testing or health behaviours?**

Design

This research study had a longitudinal design with a qualitative element. In order to address the outcomes and subsequently answer the research questions, it was necessary to use both quantitative methods and qualitative methods. When undertaking a mixed methods study, the researcher uses qualitative research methods for one phase or stage of a research study and quantitative research methods for the other phase or stage of the research study. When used in combination, quantitative and qualitative methods complement each other and allow for a more robust analysis, taking advantage of the strengths of each (Sale et al., 2002).

Researchers have argued that the complexities of most public health problems or social

interventions, such as health education and health promotion programs require the use of a broad spectrum of qualitative and quantitative methods (Sale et al., 2002).

Mixed-methods sequential explanatory design, is highly popular among researchers and implies collecting and analysing first quantitative and then qualitative data in two consecutive phases within one study (Ivankova, Creswell, & Stick, 2006).

The mixed-methods sequential explanatory design consists of two distinct phases: quantitative followed by qualitative. In this design, a researcher first collects and analyses the quantitative data. The qualitative data are collected and analysed second in the sequence and help explain, or elaborate on, the quantitative results obtained in the first phase. The second, qualitative, phase builds on the first, quantitative, phase, and the two phases are connected in the intermediate stage in the study. The rationale for this approach is that the quantitative data and their subsequent analysis provide a general understanding of the research problem. The qualitative data and their analysis refine and explain those statistical results by exploring participants' views in more depth (Ivankova et al., 2006).

Quantitative methods were used to address research questions one to six. Qualitative methods were then adopted sequentially to answer question seven with an aim to complement and try to further understand more about the patients' and dentists' views on what they thought about the method of screening that was being used and additionally, to further explain any psychological variables that might predict subsequent health behaviour following screening. The intention of this was to complement the quantitative results answering question six by having those participants who actually received the screening intervention contribute in their own words their reasons for any subsequent health behaviours following the screening intervention. Quantitative data was collected to start with. Qualitative data was only collected when a participant had completed the quantitative data collection phase.

Participants

Dental Patients

Five hundred and twenty (N=520) dental patients gave written consent to take part in the study. Participants were either NHS or private dental patients attending one of the two dental practices where study data was collected.

General Dental Practitioners

Six (N=6) General Dental Practitioners gave verbal consent to take part in the qualitative phase of the study. All dentists were fully qualified, and treated both NHS and private dental patients in one of two dental practices.

Inclusion and Exclusion Criteria

There were 3 criteria that were chosen in recruiting dental patients. They are outlined and fully justified below.

- Fluent in English language

It was important that participants could understand written and spoken English language so that they could give informed consent to participate in the research as no translation facilities were available. Additionally, the psychological measures used in the study had been written and validated in English only. Their level of understanding was assessed in two ways. Firstly, dental staff and patient notes were used to confirm any language problems. Secondly, if a dental patient arrived and confirmed they would like to participate in the research, it was checked that they had read and understood the participant information sheet sent to them with the recruitment letter. A translation service was an option which could have been considered if the measures to be used had been validated in several languages although this was not the case, and would have been costly and time consuming.

- Aged 45 or over

This age limit was set because the risk of type 2 diabetes increases with age (Harris et al., 1998), therefore it would be more likely to find those at risk by using this age limit. Additionally, this age is used as the earliest age that risk points are assigned to an individual on the risk assessment tool used in the current study. No upper age limit was set because diabetes risk does not decline again at a particular age, but also to maximise recruitment.

- No previous diagnosis of diabetes or pre-diabetes

Due to the nature of the research, participants were required not to have had a diagnosis of diabetes or pre-diabetes as the purpose was to screen for these conditions in people without a history of them.

Setting - Choice of dental practice

Data collection took place at two different locations over 118 days during September 2013 and March 2014 and between January 2015 and May 2015. There was a gap in data collection when moving and setting up the research study from one dental practice to the other and whilst the researcher was on maternity leave. An NHS dental practice in South East London, and an NHS dental practice in Staffordshire were recruited to take part in the research. Both dental practices had three Dental Practitioners seeing both NHS and privately paying patients during the recruitment period. They both conducted routine dental work as well as cosmetic dentistry, whilst the practice in Staffordshire also had a Hygiene Therapist. Dental practices were recruited through opportunistic sampling. Firstly, dental practices in the South East were contacted through professional contacts within the Dental Institute at King's College London. A dental practice in Catford, South East London was recruited first. A second dental practice was recruited in Stone, Staffordshire after contacting dental practices in the area through an information letter containing a reply slip where the Principal dentist or practice manager could return to register their interest in their practice participating in the research. The remaining participant sample was recruited at this practice. There was difficulty in recruiting dental practices, hence why there were only two practices involved in the study. Though more than fifty dental practices were contacted to participate in London and in Staffordshire, it was thought that the idea of research being conducted within a potentially busy primary care dental setting would be off-putting to dental practice owners; and this was confirmed when two potential practice owners replied to our information letter via the reply slip saying just this.

Recruitment

Quantitative phase of study

Patients were identified by dental practice staff through inspection of medical records, to ensure that they did not have diabetes, were English speakers and were aged 45 and over. Those who met these inclusion criteria and were soon to be attending for their general dental appointment were sent a letter of invitation and an information sheet explaining the nature of the research, inviting them to take part at their next appointment (see appendix 3). Due to the practice demands, it was not always possible to check the medical records for a history of diabetes or proficiency in English, therefore in some cases, in the first instance, the age limit was the only criterion used when sending invitation letters. The only negative impact this had

on the research was that some dental patients who had diabetes arrived for their appointment were unable to participate, thus recruitment letters were sent out needlessly in some cases. Overall, this did not happen that often, but when it did, the researcher was only met with keen interest from dental patients that such research was being conducted.

Due to additional interest from people who had not been formally invited to participate through the recruitment letter i.e. those patients scheduling appointments after recruitment letters were sent, the recruitment method was amended through a minor amendment approved by the National Research Ethics Service to include patients who were in clinic on the day of data collection who expressed an interest in partaking in the study but who had not received the information sheet in the post to read before they arrived at their appointment. This amendment to the recruitment method was made to allow for a more satisfactory patient experience; in that those patients who were interested in the study were able to take part in research that they were eligible for, and could receive screening for diabetes at no extra cost. Recruiting additional participants this way was not considered problematic as dental patients were still only recruited if they met the inclusion criteria, read the information sheet and provided informed consent. The amendment also meant that the sample would be more of an accurate representation of the patient population who attended the practices (rather than limited to those with a long-standing booked appointment).

Qualitative phase of the study

In order to collect qualitative data, a selection of participants was asked to take part in a semi-structured interview. Participants were selected using consecutive and purposeful sampling whereby it was specified before recruitment the kind of participants needed for interview, and then the researcher consecutively recruited those participants as they came along after completing the quantitative phase of the study. Once quantitative data was collected for a selected participant, they were contacted by telephone to ask for them to take part, being reminded and directed back to the participant information sheet which detailed this phase of the study. The purposeful sampling matrix specified a variety of risk score participants were needed, from those who did or did not have the second screening test conducted and those who did or did not visit their GP for follow up diagnostic test if needed. Having participants who fell into each of these categories meant that rich qualitative data could be compared between and within different participants with similar and different experiences. Participants could have been recruited via several other methods such as convenience sampling or

theoretical sampling but recruiting consecutively and purposefully was seen as the best recruitment method here so that the data would contribute to the specific topic of the questions, and to ensure that participants with a varied FINDRISC score were captured and those who did and did not attend for GP follow up to contribute different perspectives and experiences. Data collection continued until it reached saturation, where no new information was collected, and no new themes were identified.

Dentists were also asked to participate in the qualitative phase of the study. They were recruited via convenience sampling due to the small number of dentists working in the two dental practices where dental patients were recruited from. After all quantitative data had been collected from dental patients, dentists were approached and asked if they were available to be interviewed about the screening intervention that had been conducted. They gave verbal consent when the interview commenced and was recorded.

The interview schedule can be found in appendix 4.

Equipment and measures

Check Diagnostics A1c Now+ Multi-test A1C System -

The A1c Now+ Multi-test A1C system was used for the instant measurement of a participants' HbA1c. This equipment was selected because it provides individual testing of HbA1c outside of the laboratory. Due to recent calls for HbA1c to be used for diabetes screening (Saudek et al., 2008) and the ease of use, the kit was deemed suitable. Each kit provided 20 tests. A lancet was used to draw blood from the finger. A droplet of blood was then collected using the blood collector provided and the whole thing was then inserted into the sampler body which contains the solution to analyse the sample. Once this was mixed by shaking the unit, a test cartridge was inserted into the monitor, and once it is ready, the sampler body dispenses the diluted sample onto the test cartridge. The kit then took five minutes to analyse the blood sample, after which time the participants HbA1c result is displayed as a percentage. A1CNow+ is accessible, accurate, and easy to use (Bode, Irvin, Pierce, Allen, & Clark, 2007). Study results with health care professionals showed that the laboratory accuracy of A1CNow+ with finger stick samples was, on average, 99%. This means that, on average, a true 7.0% A1C could read approximately 6.9% A1C. An individual A1CNow+ result may differ by as much as -1.0 to +0.8% A1C from the true result. The A1CNow+ is National Glycohemoglobin Standardisation Program certified (Leal & Soto-

Rowen, 2009). Good correlations have been seen between the A1CNow+ and laboratory values with a correlation coefficients ranging from $r = 0.893$ - 0.989 (Arrendale, Cherian, Zineh, Chirico, & Taylor, 2008; Knaebel, Irvin, & Xie, 2013; Leal & Soto-Rowen, 2009).

Demographics Questionnaire -

A demographics questionnaire was designed to collect participant information such as gender, ethnicity, age, and GP information. This information was required for statistical purposes and so the GP of the participants' who took part could be contacted to inform them of their patients' involvement in the study and of their screening results (see appendix 5).

FINDRISC Questionnaire -

The FINDRISC questionnaire (Lindstrom et al., 2003) was selected as a suitable personalised diabetes risk assessment tool to use in the study (see appendix 6). Noble et al. (2011) judged the FINDRISC to be one of the most promising for use in clinical or public health practice. In contrast to other risk assessment tools such as the QDScore, intended for use by general practitioners, FINDRISC was developed as a population screening tool intended for use directly by lay people, and assesses a person's risk of developing type 2 diabetes in the next 10 years. Whilst the QDScore is composed entirely of data items that are routinely recorded on general practice electronic records (including self-assigned ethnicity, a deprivation score derived from the patient's postcode, and clinical and laboratory values) (Hippisley-Cox et al., 2009), the FINDRISC consists of 8 questions, asking about age, BMI, waist circumference, use of blood pressure medication, history of high blood glucose, physical activity, family history of diabetes, and daily consumption of fruit, vegetables and berries. It is scored between 0 and 26; scores of less than 7 suggest a person is at a low risk of developing diabetes; just 1 in 100 is estimated to develop diabetes in this risk category. Scores between 7 and 11 put an individual at a slightly elevated risk, with 1 in 25 people estimated to develop the disease. Scores between 12 and 14 put an individual at a moderate risk where it is estimated that in 6 people will develop diabetes. Scores between 15 and 20 put an individual at high risk where it is thought that 1 in 3 will develop diabetes, and scores of 20 or higher put a person at a very high risk with a 1 in 2 chance of developing the disease (see appendix 7 for scoring sheet). In a review of risk tools, it was concluded that the FINDRISC tool was currently the best available tool for use in clinical practice in Caucasian populations (Schwarz et al., 2009). Janghorbani and colleagues also reported that the FINDRISC showed a reasonably good ability to predict MetS in a cohort of first-degree relatives of patients with

T2D, with an area under the ROC of 65% (Janghorbani, Adineh, & Amini, 2013). At the time of designing the study, research suggested that further testing be conducted in participants with a FINDRISC score of 10 or higher (Tankova, Chakarova, Atanassova, & Dakovska, 2011).

An extra item asking participants about their views regarding the routine use of the measure in dental settings was added with a 6-point likert scale ranging from 0 to 5, not at all useful to extremely useful, respectively. This was added to give a simple rating of a participant's view of the usefulness of the questionnaire.

Height and Weight Equipment -

A mobile stadiometer was used to accurately measure a participant's height, and a set of digital scales was set up to check their weight so that the researcher could accurately check these measurements to calculate BMI, rather than rely on self-report.

Tape Measure –

A flexible tape measure (with centimetre units) was used to measure waist circumference. Starting at the top of the hip bone, the tape measure is brought all the way around level with the navel, ensuring it is not too tight and that it is straight. Again, this was checked rather than relying on self-report or trouser measurement.

Extended Parallel Processing Model (EPPM) questionnaire-

EPPM variables were measured using a 29-item questionnaire called 'your views about diabetes and diabetes screening', based on a scale previously used to assess PMT constructs in relation to screening for cervical cancer (Orbell & Sheeran, 1998), but adapted specifically for this study to assess beliefs surrounding diabetes and diabetes screening (see appendix 8). The questionnaire consists of 8 sub-scales, representing components of the EPPM (perceived severity of diabetes, perceived vulnerability to diabetes, fear of diabetes, rewards which may result from failing to attend their GP for a blood glucose test, barriers which may prevent attendance at their GP for a blood glucose test, belief that a blood glucose will help identify diabetes and reduce diabetes-related complications and perceived ability to attend their GP for a blood glucose test, and intention to attend their GP for a blood glucose test).

Participants were asked to what extent they agreed with each statement (e.g. "The benefits of

having a blood glucose test outweigh the costs"; "I am unlikely to have diabetes") on a 5-point likert scale ranging from 'strongly agree' to 'strongly disagree'. Item scores in each subscale were summed to produce a total score for each EPPM component (for scoring, see appendix 9). The reliability of the questionnaire was assessed using Cronbach's alpha.

Centre for Epidemiologic Studies for Depression (CES-D) Scale -

The CES-D Scale (Radloff, 1977) was used to screen participants for low mood (see appendix 10). A depression scale was selected for use in this study because mood, in particular low mood has been shown to be a reliable predictor of screening attendance (Calderwood, Basic, Kazis, & Cabral, 2013). The CES-D scale is a short self-report scale designed to measure depressive symptomatology in the general population. The items of the scale are symptoms associated with depression that have been used in previously validated longer scales (Radloff, 1977). The new scale was tested in household interview surveys and in psychiatric settings and was found to have very high internal consistency and adequate test-retest repeatability. It is also freely available to use in the public domain. The 20 item scale asked participants about their mood over the past week, for example, "I felt happy" or "I felt lonely". Scores over 16 indicate mild depression, scores over 27 are indicative of major depression. A cut-off score of 16 was used in the study and the GP of participants scoring 16 or over were informed of the result (for scoring sheet, see appendix 11).

Interview schedule –

An interview schedule was developed of questions to explore further a participant's views about screening, the process, receiving their risk result, and if appropriate any views about further screening and health behaviours. The aim of the questions was to collect insight into the views of patients to help understand better the reasons that prompted people to engage in screening and their reaction to the screening measures exposed to in the study. The intention was to additionally understand why people did or did not attend for subsequent screening at the GP and to contribute to the theoretical understanding of screening uptake in practice; a bottom up method to find out what people said actually motivated them to attend or not attend the GP, as opposed to what was predicted by psychological variables; by a top-down method which would find out the percentage of variance that is explained by a set of predictor variables. An interview schedule was also developed of questions to explore the views of dentists on the feasibility of the screening intervention conducted with dental patients (see appendix 4).

Digital recorder / Dictaphone -

A Dictaphone was used to accurately record the telephone interviews in order to allow transcription of the data afterwards.

Data collection Procedure

Figure 1 below shows the flow of participants through the enrolment process, the quantitative phase of the study and then into the qualitative phase.

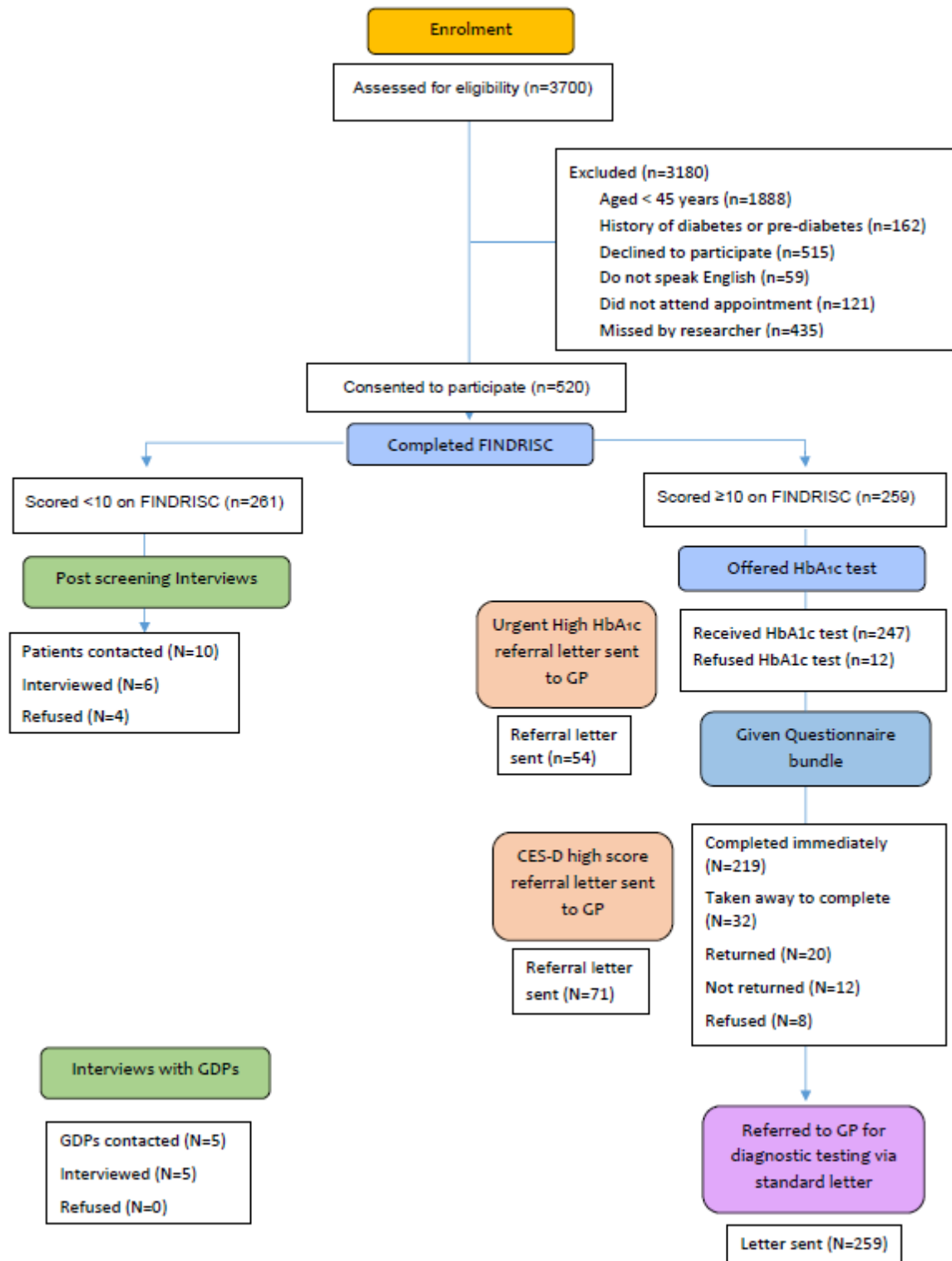
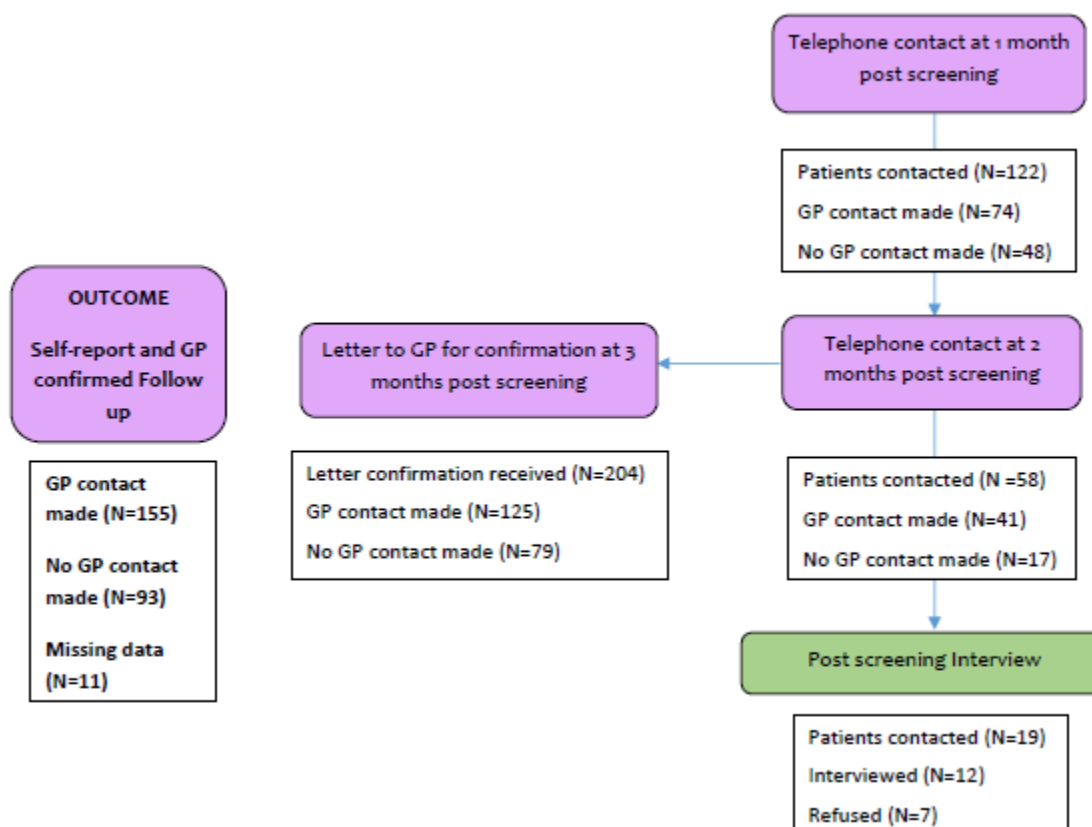


Figure 2 - Consort diagram of the flow of participants through the study



On arrival, participants wishing to take part were asked to read the patient information sheet and subsequently gave written informed consent if they wished to take part (see appendix 12 and 13, respectively). They were then asked to complete a demographics questionnaire and part of the FINDRISC questionnaire (Qs 4-8). The researcher then completed Qs 1-3 of the FINDRISC with the participant by measuring the participants' height and weight in order to calculate their BMI and took their waist measurement. The participant then proceeded to see the dentist for their routine appointment. At the end of their appointment, the participant returned to the researcher to receive the result of the FINDRISC questionnaire. The individualised risk result was fed back to participants using a pre-prepared verbal script (see appendix 14) and a written risk sheet, both of which were developed following the result of the systematic review described in chapter 3. Participants were given their individualised risk score, their risk category and subsequent absolute risk that was linked to being in a particular category, both verbally and in writing (See appendix 15).

If the participant scored less than ten on the FINDRISC they were debriefed about their low risk result, reassured and thanked for their participation. The participants' GP was informed of their participation and of the outcome.

If the participant scored ten or more on the FINDRISC (a positive result) their risk result was explained, and they were subsequently offered an HbA1c test using the A1c NOW+ kit. Those participants wishing to receive the HbA1c test were informed about the test by a member of the research team who then administered the HbA1c test in a private office. If a participant did not wish to have the HbA1c test, they were fully debriefed, thanked for their participation, and because of their risk result, were advised through a standard letter to visit their GP for a blood glucose test (Appendix 15). Further information on diabetes was provided. The participants' GP was informed of their participation and a blood glucose test was sought by letter (see appendix 16).

Participants who had the HbA1c test and showed a normal HbA1c reading ($<6\%$) were informed of what their result meant, but due to the high risk result on the FINDRISC, were still advised in person and through a debrief sheet to visit their GP for a blood glucose test. Participants who showed an elevated HbA1c reading ($>6\%$) were also informed of what their result meant, and were also advised in person and through a debrief sheet to visit their GP for a blood glucose test (see appendix 15). Their GP was also informed of the patient's FINDRISC and HbA1c results through a standard letter, and a blood glucose test was suggested (see appendix 16).

Participants who were identified as at risk of developing diabetes through either the FINDRISC alone or through the HbA1c test as well, were asked to complete a bundle of questionnaires comprising of the mood measure (CES-D scale) and the psychological measure assessing constructs of the Extended Parallel Process Model (EPPM). Participants were asked to complete the measures at the dental practice, but if they declined, they were offered the chance to complete them at home and return them to the researchers in the freepost envelope provided. If the participant scored 16 or higher on the CES-D scale, their GP was sent the standard CES-D referral letter to inform them of their patient's risk for clinical depression (see appendix 17). Additionally, a referral letter was sent to the GP if a patient scored $\geq 6\%$ on the HbA1c screening test (see appendix 18).

One month after the receipt of an 'at risk' result, participants were contacted to determine whether they had contacted their GP for a blood glucose test and what happened as a result of this contact. The researcher made a note of their responses.

For those participants who indicated that they had not visited their GP, this telephone call often acted as a reminder to contact their GP regarding further glucose testing. One month after this reminder, those participants were contacted again and their attendance at, and outcome of the recommended blood test was noted (see appendix 19 for follow-up call script).

Three months after the 'at risk' result, the researchers contacted the GP's of those participants who were asked to attend for a blood glucose test in order to verify any contact made and to obtain a definitive diagnosis. A standard letter was sent to GP's requesting the information to support any self-report data collected from the participant (see appendix 20).

For patients eligible for the qualitative study, the researcher contacted the participant via telephone to arrange a suitable time to conduct the telephone interview. Dental patients were recruited using purposive sampling. It was specified in advance the type of dental patients that were needed, therefore a method of quota sampling was used. Patients of both low and high risk were needed for sampling and of the high risk patients, both those who attended for GP follow-up and those that did not were required. Therefore, participants meeting these selection criteria were consecutively recruited as they came through the screening programme once they had completed the quantitative stage of the study. Using this method of sampling allowed for participants in each of the subgroups to be sampled.

The participant was informed that the interview was being recorded and they gave additional verbal consent after giving written consent earlier in the study. The interview followed the structure of the interview schedule, and once all questions had been answered, the participant was thanked and the interview recording was stopped. All participants were interviewed over the phone and the data was recorded using a Dictaphone. Data was transcribed verbatim immediately after each interview was conducted. It was then played back and checked against the transcription notes to ensure its accuracy.

The interviews took place over the telephone for dental patients. Semi-structured interviews were conducted and recorded using a digital voice recorder. Questions were open-ended and asked dentists and patients about their experiences of the screening programme conducted. Question format was designed to use open-ended descriptive questions which were not fixed but were allowed to develop as a result of the exchange between the participant and the researcher.

Dentists eligible for the qualitative phase of the study were invited to participate in a face-to-face interview. GDPs were sampled opportunistically; other sampling methods were considered such as random sampling and snowball sampling, but due to the small number of practices and subsequently, the small number of GDPs where the screening programme was carried out, these methods were not possible. After agreeing, they were informed that the interview was being recorded and they gave verbal consent. The interview followed the structure of the interview schedule, and once all questions had been answered, dentists were thanked and the interview recording was stopped. Data was transcribed verbatim immediately after each interview was conducted. It was then played back and checked against the transcription notes to ensure its accuracy.

Risks of the Study

There were no additional risks or burdens other than the need to complete the questionnaire bundle after the dental appointment and receive the finger-prick HbA1c blood test. The receipt of personalised risk information may have caused some worry to several participants, nevertheless, patients were given the time to discuss how they felt about their risk of diabetes with a member of the research team and were also be given details of the research team for further contact, if they felt it necessary.

Incentive and Benefits

Although there was no monetary incentive, participants were given the opportunity to be screened for diabetes whilst attending for a routine dental appointment which they would not usually have been offered. Therefore, there was a potential benefit for early detection, intervention and treatment if a participant was found to have diabetes.

Confidentiality

Participant data were stored on encrypted secure electronic media. A separate file recording participant contact details was protected by password. All personal data of participants were stored on password protected computers at the University. Paper copies of questionnaire data were stored in secure locked filing cabinets in a locked office. Personal data held on password-protected university computers, were anonymised.

Research Ethics

The study was reviewed and given a favourable opinion by the National Research Ethics Service Committee West Midlands- Black Country in August 2013. The letter giving permission for the study to take place appears in appendix 21.

Statistical analysis

Quantitative analysis

IBM SPSS Statistics® Version 22 (Statistical Package for the Social Sciences) was used to analyse the quantitative data. All of the data were inputted into one dataset.

In order to determine how many participants were needed for the study, a sample size calculation was performed on the primary outcome. A prevalence rate of 10% for diabetes and pre-diabetes was assumed based on published prevalence of diabetes of 5% and an assumed prevalence of pre diabetes of another 5%. Additionally, published data evaluating the FINDRISC as a screening tool and demonstrating specificity and sensitivity of the FINDRISC of .7 was considered (Tankova et al., 2011). N=520 participants were therefore needed so that we could expect N=176 participants to be at risk and needing to be referred to their GP for a diagnostic test. This sample size would then allow for approximately 80% power, and around a probability of .05 of participants actually attending the GP for a diagnostic test.

Data was screened and preliminary analyses relating to parametric assumptions for particular tests were conducted. Descriptive and inferential statistics were used to address all quantitative research questions. Frequencies were used to calculate the number of people participating in screening, and to calculate the number of those at risk of diabetes based on FINDRISC alone and FINDRISC and A1C results.

Descriptive statistics were used to calculate the proportion of patients who attended the GP after being advised to do so as a result of their risk result. Pearson's Chi square test was used to determine if attendance at the GP was informed by the type of test taken, or the test result.

Participants were only referred to their GP if they had a positive risk result (that being ≥ 10 on the FINDRISC measure and either no result or any HbA1c result from the finger prick measure). Therefore, not all of the study sample data needed to be analysed to answer the research question. However, in order to conduct the chi square test, a 2 x 2 contingency table needed to be created, therefore, the categorical predictor variable; patients referred to their GP needed to have two categories, and so did the categorical outcome variable; GP attendance. The two categories for the predictor variable were, GP referral based on a risk result from a positive FINDRISC measure alone (≥ 10 on the FINDRISC measure and either no result or $< 5.7\%$ result from HbA1c finger prick measure), and GP referral based on a risk result from a positive FINDRISC and positive HbA1c measure (≥ 10 on the FINDRISC and $> 5.7\%$ from HbA1c finger prick measure). It was decided that these two categories were of interest to see if having either one or two positive risk screening results would have an effect on whether participants went to see their GP as advised. Therefore, the predictor variable was called patient risk result. The outcome variable also had two categories. In order to analyse the data on GP attendance, it was necessary to combine data that had been collected from participants and their GP. One overall outcome variable was created; Contact made with GP; this therefore had two categories; yes – contact made and no- no contact made. This outcome variable was created by combining patients' self-reported response to whether they had seen their GP and responses made from contacting GPs to find out what the outcome of our referral was, if there was data from both the patient them self and the GP. In some cases, there was only self-report data, and in others, only the GPs response. Therefore, in some cases there was no option but to rely on the self-report data despite its drawbacks. Where there was a response from both patient and GP, it was checked whether both responses corroborated. In cases where they didn't, the GP response was taken as correct. This variable yielded several kinds of responses ranging from participants having made no contact at that point, having an appointment in the near future, having seen the GP and now awaiting blood tests, to having seen the GP and had diagnostic test results back and having seen the GP who advised it not necessary to follow up the screening with diagnostic tests. The latter response made it difficult to code the data; the participants had in fact followed the

recommended advice to see their GP, however, the GP did not conduct a diagnostic test. Therefore, it was decided that some level of GP contact, whether it be having made an appointment to see the GP or having had an appointment or had a diagnostic test was acceptable as having followed the advice to see the GP following the screening tests conducted at the dental practice. The outcome variable was renamed; Contact made with GP.

To assess the psychological profile of those at risk of developing diabetes, the psychological variables measured were CESD scores, a measure of depression, and EPPM variables: fear, intention, self-efficacy, severity, vulnerability, response costs, response efficacy, and rewards for maladaptive response. Data for these variables were only collected from dental patients who were at risk of developing diabetes following the screening tests conducted. Therefore, it was not possible to compare those patients at risk to those not at risk on these psychological variables. Means and SDs and minimum and maximum values were reported. To assess any apparent differences inferentially, independent samples t-tests were conducted to compare those who contacted their GP for diagnostic testing with those who didn't, on these psychological variables.

In order to predict whether any of the study variables were predictors of patient contact with the GP following a positive risk screening result, a binary logistic regression was conducted. Logistic regression is used when an outcome variable is categorical as opposed to continuous as with multiple regression, and predictor variables that are either continuous or categorical (Field, 2013). Binary logistic regression predicts which of two categories a person is likely to belong to given certain other information; in this case whether someone is likely to make contact with their GP based on psychological variables.

Following statistical advice, a stepwise regression method was adopted. Stepwise regression was deemed appropriate as the study did not have any firm theoretical predictions about the relative value or importance of each of the predictors used here. Therefore, the order of the predictor variables was entered into the model was based on mathematical criteria conducted in SPSS. The predictor variables were entered using the backward likelihood ratio method as follows: CES-D score, and the eight EPPM variables; fear, intention, self-efficacy, severity, vulnerability, response costs, response efficacy, and rewards for maladaptive response. The backward method begins with all predictors included in the model and removes predictors if their removal is not detrimental to the fit of the model. When using the stepwise method, the

backward method is preferable because forward methods are more likely to exclude predictors involved in suppressor effects (Field, 2013). The outcome variable was, contact made with GP.

The psychological measures were assessed for internal consistency. Cronbach's alpha was performed on the CES-D scale and each of the subscales on the EPPM measure. Cronbach's Alpha could not be calculated for the EPPM Severity subscale as this subscale only had one item. Cronbach's α for each scale and subscale calculated are reported in chapter 5.

Qualitative analysis

Question format was designed to use open-ended descriptive questions which were not fixed but were allowed to develop as a result of the exchange between the participant and the researcher.

Inductive thematic analysis was used to analyse the individual interview transcripts. Thematic analysis is a method for identifying, analysing and reporting patterns within data (Braun & Clarke, 2006). In contrast to qualitative analytic approaches such as interpretative phenomenological analysis or grounded theory, thematic analysis is not wedded to any pre-existing theoretical framework (Braun & Clarke, 2006).

Analysis of the interviews followed closely the six phase process outlined by Braun and Clarke (2006), which involved familiarising oneself with the data, generating initial codes, searching for and reviewing themes, defining and naming these themes, and finally producing the reports. The themes were checked by another member of the research team to ensure credibility of the interpretation and validated through discussion and reading through the transcripts. Once themes had been identified for both dentist and patient data, they were combined for discussion purposes where similarities existed between both sets of themes. This was simply done by linking similar themes and discussing both in the same context.

This approach was adopted as the overall aim of the study was to explore dentists and patients views and experiences and therefore it represents a useful tool through which patterns and themes within the dataset can be identified and described.

Other analytic methods of qualitative data analysis such as Grounded theory and Interpretative Phenomenological Analysis were considered. However, whilst these two methods seek patterns in the data, they are theoretically bounded. In the current study, the

aim was not to develop a new theory. Therefore, inductive thematic analysis was used from a realist/ essentialist epistemological point of view as opposed to a constructivist point of view because experiences and meanings of the participants were to be gathered. In order to undertake the inductive analysis at the semantic level the responses to the questions were transcribed, read and re-read, with dominant and contrasting features of the data being coded manually.

Themes were generated to form links between the separate codes and reviewed to check for consistency by KB. Final themes were then produced upon further refinement and discussion with KA. In undertaking the analysis, it was found that the data generated by the respondents was sufficient to allow theoretical saturation to take place and for all the themes to be well formulated. To ensure the credibility of the qualitative research, once the themes had been formulated, the transcribed data was re-read and checked again with the themes created in mind. Ideally, this would have been conducted by a second, independent researcher, but there were insufficient resources for this. As the screening, interviews and analysis were conducted by one researcher, a reflexive commentary was written and included in the discussion of this chapter. Credibility could have also been assessed by using member checking, whereby participants' judge how well the results describe the participants' perspective. The researcher aimed to enhance transferability of the qualitative data by clearly describing the research context and the assumptions that were central to the research so that the results might be generalizable.

Themes or patterns within data can be identified in one of two primary ways in thematic analysis: in an inductive or 'bottom up' way, or in a theoretical or deductive or 'top down' way (Braun & Clarke, 2006). Inductive thematic analysis was used here because an inductive approach means the themes identified are linked strongly to the data themselves (Patton, 1990), and is a process of coding the data without trying to fit them into a pre-existing coding frame, or the researcher's analytic preconceptions (Braun & Clarke, 2006). It is also a useful method due to its flexibility and theoretical freedom, along with its ability to create a detailed account of data (Braun & Clarke, 2006).

Finally, for the purpose of a discussion of the findings from the current study as a whole, the quantitative and qualitative findings were combined to see the study findings as a whole.

In summary, this thesis used quantitative methods to explore RQ 2-6, and qualitative methods to explore RQ7. Chapter 5 that follows reports on RQ2, 3 and 4, chapter 6 report of RQ5 and 6, and then chapter 7 reports on RQ7.

Chapter 5

Uptake of Screening for Diabetes Risk in General Dental Practice, and the effect of diabetes risk communication on subsequent health behaviour.

Background to the Chapter

The literature review in chapter 2 highlighted the fact that screening for diabetes is likely to bring about benefits rather than cause psychological harm. It was further argued that screening in non-traditional settings such as the opticians and the dental practice was an option that might be acceptable to patients seen in that setting. It was also argued that screening for diabetes can be done in either invasive or non-invasive ways, however the use of both measures and the uptake of each in non-traditional, dental settings has not yet been explored. Chapter 3 then systematically reviewed literature in the area of risk communication to find the best possible way to communicate the risk of diabetes to dental patients so that if advised to do so, they followed up screening with a diagnostic test at their GP practice.

This chapter presents data on the uptake of diabetes screening by dental patients at the dental practice, describes how dental patients are at risk of developing diabetes through receiving screening tests. Following an ‘at risk’ diabetes screening result, patients were advised to seek a diagnostic blood test from their GP. Health advice is not guaranteed to be followed up or accepted by a patient. When a person is faced with a health threat, they must make a decision as to whether they will address the risk or ignore it. This chapter examines the extent to which the recommendation of diagnostic testing was taken up by patients found to be at risk of diabetes.

Introduction

T2D has become a huge burden for the adult population with ever-increasing prevalence (Wild et al., 2004), however, there is no screening programme policy in place in the UK despite the fact that detecting diabetes early on is key to health outcomes (Harris & Eastman, 2000).

Screening for diabetes can potentially allow for early diagnosis and treatment, which can prevent diabetes-related complications (Marre & Travert, 2010). Although screening for

disease can sometimes have adverse effects on an individual, screening for diabetes has been shown not to have any long-term adverse effects (Adriaanse et al., 2004). Therefore, it is suggested that screening for diabetes is essential to identify diabetes and importantly, its precursors, earlier and more efficiently.

Diabetes can be screened for using a variety of methods; in addition to traditional diabetes screening methods such as the Oral Glucose Tolerance Test (OGTT) where patients are required to consume glucose and then have blood samples taken afterward to determine how quickly the glucose is cleared from the blood, the use of HbA1c as a measure of glycaemic control over the past 12 weeks, has also been recommended as a viable means of diagnosing diabetes (Saudek et al., 2008). Although an invasive test, as it requires a sample of blood, fasting is not needed for A1C assessment and no acute perturbations (e.g., stress, diet, exercise) affect A1C. A1C is said to capture chronic hyperglycemia better than two assessments of fasting or 2-h oral glucose tolerance test plasma glucose, it is better associated with chronic complications than FPG (Bonora & Tuomilehto, 2011). However, diabetes is clinically defined by high blood glucose and not by glycation of proteins, and within-day biological variability of plasma glucose might unveil disturbance of glucose metabolism (Bonora & Tuomilehto, 2011).

Furthermore, whilst traditionally HbA1c tests require laboratory facilities to take place, the recent introduction of point of care measurement through finger prick devices has made the measurement of A1c more accessible (Sicard & Taylor, 2005; Wensil, Smith, Pound, & Herring, 2013). Point-of-care HbA1c testing systems are relatively new to the market, but there are a handful of monitors available for HbA1c evaluation, with the primary advantage being the readily available result. Some provide a result within minutes, while others use a mail-in laboratory with the result available in days. HbA1c is routinely used for assessment of control and treatment rather than as a screening tool for diagnosis (Sicard & Taylor, 2005), however, it has practical advantages and is less burdensome than the OGTT, and may therefore be associated with a higher participation in screening. One particular study investigated the difference in the uptake between 18–60-year-old South Asian Surinamese men and women offered screening by means of an HbA1c measurement and those offered screening by means of an OGTT (van Valkengoed, Vlaar, Nierkens, Middelkoop, & Stronks, 2015). Among men and women and across age groups, the authors found a higher response and participation among those invited for screening by means of an HbA1c measurement

than among those invited for a screening consisting of an OGTT; in line with the assumption that a more burdensome test is associated with a lower response (Malkani & Mordes, 2011). Ideally, a screening method efficiently identifies people with previously undiagnosed type 2 diabetes mellitus and, in light of the potential effectiveness of early lifestyle intervention (Schellenberg, Dryden, Vandermeer, Ha, & Korownyk, 2013), people at risk of T2D (e.g. those with prediabetes). Based on the higher uptake, an invitation for screening by means of an HbA1c measurement would seem a better strategy than screening by means of an OGTT (van Valkengoed et al., 2015).

Cagliero and colleagues evaluated the improvement in patients' glycemic control as a result of an immediately available HbA1c value (Cagliero, Levina, & Nathan, 1999). The improvement in glycaemic control was studied in 200 insulin-treated patients with diabetes utilizing a point-of-care monitor. Patients were randomized into 2 groups. One group had the HbA1c result immediately available at their visit, and treatment changes were done prior to the patient leaving the office. The second group had their HbA1c measured at the laboratory, and treatment changes were done via telephone or follow up visit. At the 6-month follow-up, the immediate-assay group had statistically significant improvements in their HbA1c values ($p < 0.01$). Sicard and Taylor (2005) compared a point-of-care HbA1c monitor with standardised laboratory testing. Twenty-three patients with diabetes were required to obtain both a standardised laboratory HbA1c evaluation and a point-of-care A1c Now value within a week of each other. Results showed the A1c Now monitor to be well correlated ($r = 0.758$) with the standardised laboratory test. The authors found that the most accurate A1c Now values were within a range of 6–8%. However, the results obtained in this study were not as positive as those published by the manufacturer of the A1c Now kit. A possible confounder may be that participants in the study were allowed up to a 7-day period between HbA1c evaluations, therefore, it is unclear how much the value would change within that time.

One particular point-of-care technology is the A1cNow+ test kit. It is a small, portable, disposable handheld immunoassay device which is certified by the National Glycohemoglobin Standardisation Programme, and is Clinical Laboratory Improvement Amendments (CLIA) waived. Requiring no calibration, it uses a small (5µl) blood sample that is mixed with a reagent provided with the test kit, and then transferred with a pipette to a sample well in the testing device (Bode et al., 2007). Results are then provided in 5 minutes. Although some studies have demonstrated that the A1cNow assay results are not comparable

to those obtained in laboratory studies (Schwartz, Monsur, Bartoces, West, & Neale, 2005), other studies have found a high level of such comparability (Bode et al., 2007). In addition, the ease of use of the A1cNow test kit has been examined among both healthcare professionals and lay users in achieving accurate HbA1c measurements (Chang et al., 2010).

Diabetes is known for its long pre-diabetic period. Research has demonstrated that intervention at prediabetic state such as medication or lifestyle modifications can prevent or at least delay the progression of the disease, meaning the identification of those at high risk of T2D is warranted to allow for timely action to reduce risk (Paulweber et al., 2010). Measuring plasma glucose or glycosylated haemoglobin levels has so far been recommended methods for screening the general population, however, as well as being invasive, they are said to be costly and time consuming and therefore not suitable for mass screening. Additionally, because they solely measure glycaemia they may detect diabetes too late when complications of the disease are already occurring (Haffner, Stern, Hazuda, Mitchell, & Patterson, 1990).

Alternative methods of Screening

Many attempts have been made to develop simple, fast, non-invasive and practical screening tools for identifying those at high risk of developing T2D in the future (Makrilakis et al., 2011). Validated risk calculators to quickly identify and subsequently follow-up people at a high risk of T2D are also now recommended by several international organisations (Alberti et al., 2007; Paulweber et al., 2010).

One alternative to an invasive blood test is the validated Finnish Diabetes Risk Score (FINDRISC). FINDRISC is a non-invasive screening tool that provides a measure of the probability of developing type 2 diabetes over the next 10 years (Lindstrom et al., 2003). It has traditionally been used as a predictor of T2D. It is a brief questionnaire consisting of several questions about variables correlated with the risk of developing diabetes: age, body mass index (BMI), waist circumference (WC), physical activity, dietary consumption of fruits, vegetables, and berries, use of antihypertensive medication, history of high blood glucose, and family history of diabetes. FINDRISC has been successfully implemented as a practical screening instrument to assess diabetes risk and to detect undiagnosed T2D in

European populations (Tankova et al., 2011; Wang, Stancakova, Kuusisto, & Laakso, 2010; Witte, Shipley, Marmot, & Brunner, 2010), and its reliability and validity have been clearly established (Gomez-Arbelaez et al., 2015; Janghorbani et al., 2013).

Screening for diabetes in the dental setting

Opportunistic screening is carried out at a time when people are seen by health care professionals, for a reason other than the disorder in question. Screening for diabetes can be carried out in various health settings (Howse et al., 2011b). As diabetes is recognised as a significant risk factor for serious, progressive periodontal disease (Southerland et al., 2005) and as periodontal disease may contribute to the progression of impaired glucose tolerance to diabetes (Dunning, 2009), the dental setting seems like a plausible context for the identification of people at risk for diabetes. Additionally, dentists have an important role in detecting and preventing oral and systemic diseases both because of their diagnostic and screening abilities and the frequency of patient visits (Tavares et al. 2012).

Recent research from the US has examined the usefulness of screening for diabetes in dental settings. Four US studies (Bossart et al., 2016; Genco et al., 2014; Greenberg, Kantor, Jiang, & Glick, 2012b; Herman et al., 2015) reliably supported the notion that screening for pre-diabetes and diabetes using a combination of invasive and / or self-report methods was feasible, acceptable to patients and the dental team and effective in US dental offices.

In the U.K., dental surgeries are highlighted in the 2012 NICE guidance Preventing type 2 diabetes: risk identification and interventions for individuals at high risk, as a suitable setting in which to encourage people to have a T2D risk assessment. Dentists already offer lifestyle advice to their patients as part of a preventive package of care. By extending this to cover general healthy eating and activity advice a broader reach of effect is offered to the patient; thereby addressing not only their oral health but also behaviours which may increase risk of type 2 diabetes and cardiovascular disease through the common risk factor approach. Dentists are not going to diagnose or treat a systemic disease but early detection will result in better medical and dental outcomes and it is the dentist's role to help reduce the incidence and adverse impact of diabetes (Ali & Kunzel, 2011). When screening is only opportunistic, the screened positive cases are usually subjected to undergo confirmatory tests by different methods to confirm the diagnosis. But, whether the individual will return another day to

undergo the said tests is uncertain (Savitha, Gopalakrishnan, Umadevi, & Rama, 2016). In a recent UK study, Wright and colleagues were the first to assess the feasibility of implementing a T2D risk screening pathway in dental settings using the NICE guidance tool. The validated tool in the NICE guidance was used to determine risk. This included a questionnaire and BMI measurement used to determine a risk score. Patients were rated low, increased, moderate or high risk. A total of 166 patients took part in the pilot; twenty-six low risk patients (15.7%), 61 increased risk patients (36.7%), 49 moderate-risk patients (29.5%) and 30 high-risk patients (18.1%) were identified. The findings suggested that people at risk of developing T2D could be identified in primary, community and secondary dental care settings (Wright et al., 2014). However, notwithstanding the manpower challenges facing dental teams and the fairly low uptake of further screening by patients, the identification of diabetes in dental practices was possible. One explanation for the low uptake of further diagnostic testing in this study could be the fact that patients tend to judge the severity of the illness by cues such as the complexity of the diagnostic tool used. In the case of diabetes in particular, previous work (Parry et al., 2006) showed that diabetes patients used their diagnosis journey to judge how serious their diabetes was; the more complex the diagnosis, (where for e.g. the diagnosis was made by a hospital consultant rather than a GP) the more serious patients thought their diabetes was.

On the basis of these findings, supplementing a self-report diabetes risk assessment with a more invasive, instant HbA1c blood test might be an acceptable method of diabetes screening in UK dental practices. The extent to which this is the case however, remains unexplored. The number of screening tests conducted or the more invasive the screening test it, might influence how serious they perceive their risk to be and whether that person sees their GP following screening.

The previous study also only followed up patients four weeks after the initial screening tests. Considering the length of time it can take to get an appointment at the GP surgery, this short follow up period might not have been able to capture all those who might not have had an appointment yet. Additionally, follow up in the previous study relied solely on self-report of patients which might not be accurate. Finally, the detail as to how diabetes risk was communicated to patients was not detailed in the previous study's methods therefore it is not clear if how the risk is communicated has an effect.

Study Aims

The study aimed to screen patients for diabetes whilst attending their routine dental appointment. Screening was conducted initially by a questionnaire, which aimed to assess a person's risk of developing diabetes and if necessary, a further screening test measuring a participant's HbA1c was offered, to further identify individuals at risk for developing diabetes. It is important to communicate the risk of diabetes to the individual in an effective way to maximise the chance that individuals will follow up the initial screening with further diagnostic tests in General Practice. Since the systematic review described in Chapter 3 identified certain individualised risk communication strategies that appear to increase screening uptake and its psychological predictors, these strategies were used to communicate individualised diabetes risk to individuals attending dental practices for routine dental appointments and diabetes screening were utilised.

This study builds on recent work in the field by assessing dental patients' risk of developing diabetes through a non-invasive self-report questionnaire; the FINDRISC, and whether if offered an invasive 'point of care' HbA1c blood screening test they accept.

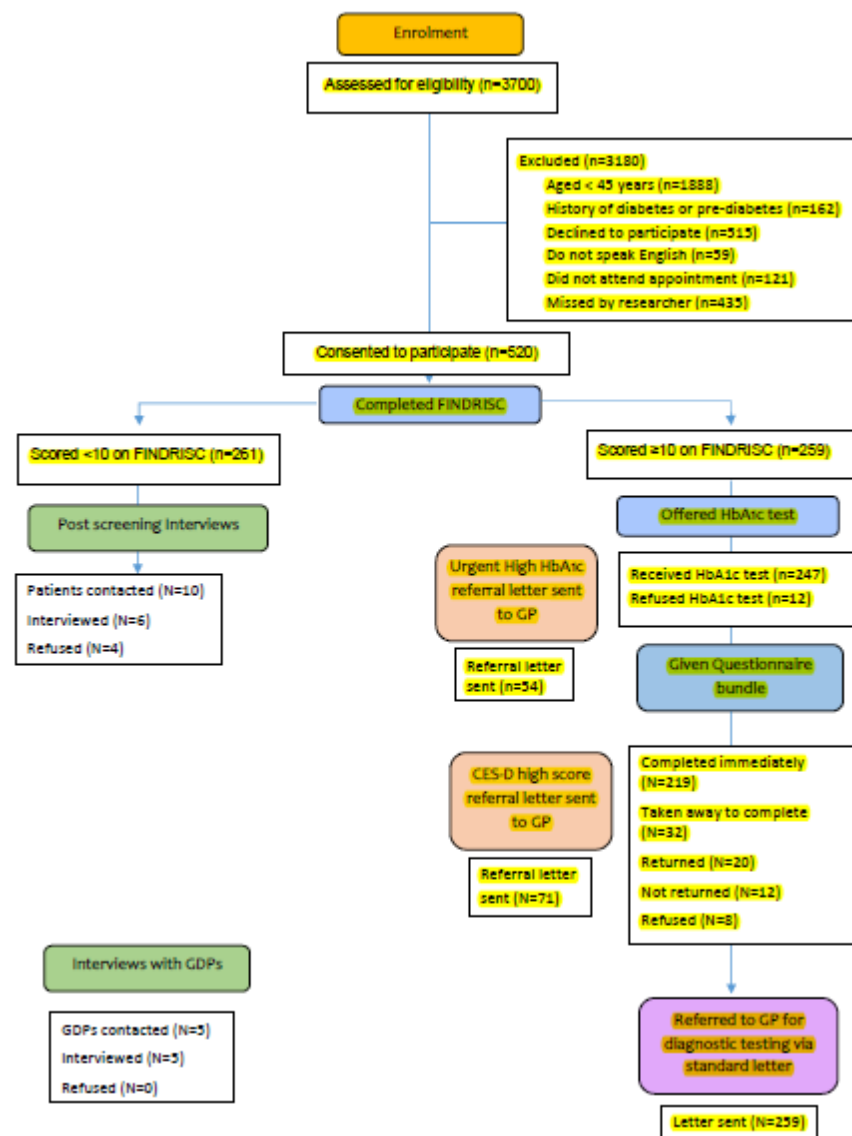
The objective of this study was to determine the uptake of patients using the Finnish Diabetes Risk Score (FINDRISC) and HbA1c information as preliminary screening tools in general dental practice, in screening for possible diabetes, and determine the number of patients at risk of diabetes. Further, the study also aimed to explore whether those participants who were advised to see their GP for a diagnostic test following an increased risk result from the FINDRISC screening measure alone or the FINDRISC and HbA1c screening measures followed the recommendation to do so. In doing so, the study aimed to answer the following research questions in bold as set out in the PhD aims and objectives (Chapter 1):

1. What is the most effective way to communicate individualised risk information to increase screening participation or its psychological predictors?
2. **What proportion of dental patients accept an offer to be screened for type 2 diabetes in a primary care dental setting?**
3. **What is the risk of type 2 diabetes in primary care dental patients as assessed through self-report and physiological measures?**

4. What is the effect of personalised diabetes risk communication on subsequent health behaviours?
5. What is the psychological profile of patients at risk of diabetes?
6. To what extent do psychological variables predict post-screening further testing or health behaviours?
7. What are patients' and dentists' views on screening for diabetes in dental settings, and can this help to further explain post-screening further testing or health behaviours?

Methods:

A thorough description of the study method is presented in chapter 4; Methods chapter.



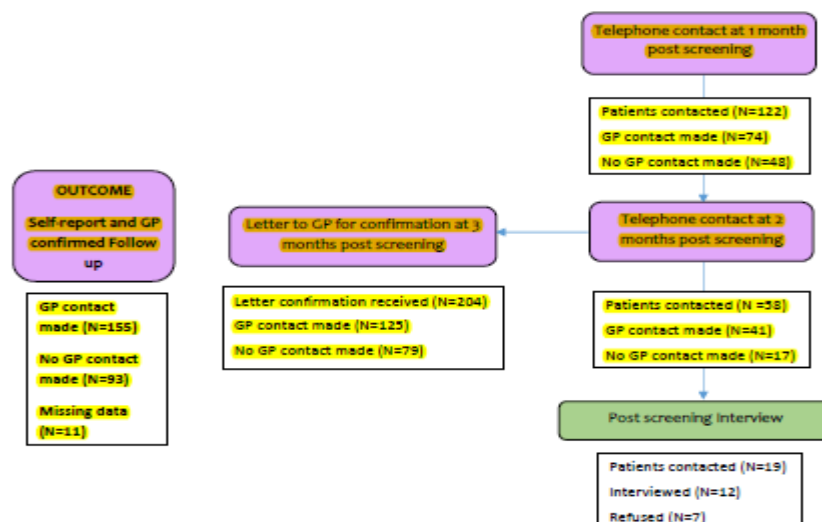


Figure 3- Flow diagram of study method highlighted to indicate relevant methods for this part of the study

The image above represents the part of the study that is applicable to this chapter and is highlighted in yellow.

Results:

The results below are set out by research question. The results demonstrate the number of dental patients who consented and agreed to be screened for diabetes when attending a routine dental appointment. It also reports the risk of diabetes in those participating and completing the screening measures. Finally, results are presented on the number of participants attending their GP practice for subsequent follow-up diagnostic tests.

Research question 2

What proportion of dental patients accept an offer to be screened for type 2 diabetes in a primary care dental setting?

Data were collected on the number of people who were eligible to take part in the study. These data appear in a flow chart, as Figure 1 in chapter 4 showing the flow of participants through the study.

The data were obtained from two dental practices in two geographically different areas of England. N=244 of consenting participants were recruited from a dental practice in Catford,

South East London. N=3700 NHS and private patients were seen by six General Dental Practitioners during the nine-month recruitment period. N=1292 patients who were eligible for inclusion based on the age eligibility criteria, attended routine dental appointments over 118 days of recruitment at two General Dental Practices in the UK. N=59 of these patients did not speak fluent English and a further N=162 already had diabetes or Pre-diabetes as assessed through dental notes and patient self-report, and were therefore excluded from the study. N=515 patients refused to participate whilst N=520 patients agreed to participate, consented for screening and completed the FINDRISC screening questionnaire. Reasons for refusal to participate included, having a recent blood glucose test, a recent health check-up such as the Well Man's Check arranged through the GP, dental pain and fear, and lack of interest in the research. Table 1 below reports the recruitment statistics for two samples of participants from Catford, Stone and overall. Looking at the table it would seem that the number of participants eligible for participation, those refusing to participate, and those excluded by the criteria set were similar between both locations.

Table 3 - Recruitment statistics of the two samples of participants recruited in Catford, Stone, and overall.

Recruitment details	Practice		
	Overall	Catford	Stone
Assessed for eligibility (N)	3700	2127	1573
Declined participation (N)	515	304	211
Excluded for age (N)	1888	1141	747
Excluded for history of diabetes (N)	162	91	71
Did not speak English (N)	59	55	4
Did not attend (N)	121	68	53
Missed by researcher (N)	435	224	211
Consented to participate (N)	520	244	276

Table 4 shows demographic characteristics of the two samples of participants recruited in Catford, Stone and overall. N=276 (53.1%) participants consented and participated at the dental practice in Stone, Staffordshire. Of the 520 participants, N=374 (71.9%) were NHS dental patients, whilst N=146 were non-NHS dental patients. The participant sample consisted of slightly more females than males with N=304 (58.5%) female participants. The mean age of the sample was 58.8 years, with a range of age from 45 years to 86 years. In terms of ethnicity, 73.1% of the sample considered themselves to be White British (N=380). Demographic information overall and separately by practice, is given in Table 2 that follows. Whist ethnicity information was collected in detail using the recommended ethnic group question (The Office for National Statistics, 2015), for the purpose of reporting the samples ethnic background, they were grouped into the categories stated by The Office for National Statistics (2015).

Table 4 - Demographic characteristics of the participants recruited from Catford, Stone and overall.

Demographic characteristic		Practice		Sig (p.)
	Overall	Catford	Stone	
Age M years (SD)	58.83 (9.56)	56.11 (8.79)	61.24 (9.59)	<.01
Gender (N)				
Male	216	104	112	.64
Female	304	140	164	
Funding status (N)				
NHS	374	150	224	<.01
Private	146	94	52	
Ethnicity (N)				
White	409	146	263	<.01
Mixed / Multiple ethnic groups	22	19	3	
Asian / Asian British	22	13	9	
Black / African / Caribbean / Black British	61	60	1	
Other ethnic group	6	6	0	

Mean FINDRISC Score (SD)	9.92 (4.10)	10.10 (4.48)	9.76 (3.74)	.35
FINDRISC score (N)				
<10	261	121	140	
>10	259	123	136	.79
FINDRISC risk score category (N)				
< 7 LOW risk	101	51	50	
7-11 SLIGHTLY ELEVATED risk	247	101	146	
12-14 MODERATE risk	108	55	53	
15-20 HIGH risk	63	36	27	
>20 VERY HIGH risk	1	1	0	.07
Mean HbA1c score (SD)	5.67 (.50)	5.61 (.54)	5.72 (.45)	.07

On the basis of the results above, it was decided that the data from both locations would be combined for the rest of the analysis.

The next section of the results presents data on the risk of diabetes and answers the following research question-

Research Question 3

What is the risk of type 2 diabetes in primary care dental patients as assessed through self-report and physiological measures?

Around half of those recruited [N=261 (50.2%)] scored below the cut-off score of 10 on the FINDRISC questionnaire, and therefore were not offered any further screening. N=259 (49.8%) patients were found to be 'at risk' of developing diabetes based on the cut off FINDRISC score of 10, and were therefore offered the further screening test, and were subsequently referred to their GP for formal diagnostic testing.

Table 5 shows the number of participants who fell into each risk category based on their FINDRISC score. The most popular risk category with 47.5% of participants was the slightly elevated risk category, where N=247 participants scored 7-11 on the FINDRISC. The mean FINDRISC score was 9.92, where the lowest score reported was 2 and the highest score was 23.

Table 5 - Number of participants and Mean HbA1c score by FINDRISC risk score category

FINDRISC risk category	N	Mean HbA1c score
< 7 LOW risk	101(19.4%)	n/a
7-11 SLIGHTLY ELEVATED risk	247(47.5%)	5.61%
12-14 MODERATE risk	108(20.8%)	5.73%
15-20 HIGH risk	63(12.1%)	5.67%
>20 VERY HIGH risk	1(0.2%)	5.60%
TOTAL:	520	
FINDRISC score of ≥ 10 as current cut off for further screening	259(49.8%)	5.67%

Table 5 shows the number of participants falling into each FINDRISC risk score category. It appears that the majority of participants fell into the slightly elevated risk category. When using the recommended cut off score available at the time of the study of 10, N=259 scored 10 or higher and therefore were identified as being at risk of developing diabetes.

Of the N=259 found to be at risk of developing diabetes, N=241 received the further screening HbA1c test, whilst N=18 refused this further screening test. Based on cut off values, N=123 had an HbA1c of lower than 5.7% suggesting it was unlikely that they had diabetes. N=46 were found to be at risk of pre-diabetes with an HbA1c score of between 5.7-5.9%, N=54 had a score of 6.0% or higher suggesting they may have diabetes. The mean HbA1c score was 5.67%.

The final section of the results presents data on the effect that receiving an ‘at risk’ result on the screening measures had on participants in terms of their subsequent actions and answers the following research question-

Research question 4: What is the effect of personalised diabetes risk communication on subsequent health behaviours?

Based on FINDRISC and HbA1c scores, 259 participants were advised to see their GP for a diagnostic test. Of those 259, N=124 had a positive FINDRISC and a negative A1c, N=118 had both a positive FINDRISC and positive A1c result, and N=17 had a positive FINDRISC but refused the A1c test.

Of N=259 advised to do so, N=155 made contact with their GP, N=93 did not, and there was no outcome data for N=11.

Assumptions for a chi square test were checked. The data had independence and the expected frequencies were above 5. With a 2 x 2 contingency table, no expected values should be below 5, in order to not reduce the power of the test.

Table 6 - Frequencies of participants making contact with their GP by type of positive risk result received

Contact made with GP	<u>Patient Risk Result</u>		<u>TOTAL</u>
	Positive FINDRISC + Positive A1c result	Positive FINDRISC + Negative A1c result (or refused test)	
Yes	88	67	155 (59.85%)
No	26	67	93 (35.91%)
	114	134	
N=11 patients had no follow up data			

Table 6 shows the number of cases which fell into each combination of categories. N=118 patients were referred to their GP with a positive FINDRISC and a positive HbA1c risk result, N=88 of these patients made contact with the GP, whilst 26 did not. There was no patient or GP response for N=4 of these patients. As the table shows, N=141 dental patients were referred to their GP with a positive FINDRISC risk result but either a negative HbA1c

risk result or no risk result due to the test being refused. Of these N=141, N=67 patients made contact with their GP, whilst 67 did not.

There was a significant association between the type of risk result being referred to GPs and whether or not a patient would follow recommendation and contact their GP. $\chi^2(1) = 19.43$, $p < 0.0001$. The number of positive risk scores was significantly associated with GP contact; patients were more likely to contact their GP if they had received two positive risk scores.

Based on the odds ratio, the odds of patients contacting the GP was 3.38 times higher (95% CI [1.95, 5.89]) if they were referred with two positive risk results (both a positive FINDRISC and positive HbA1c risk result) as opposed to just one (a positive FINDRISC but negative or no HbA1c). An indication of statistical significance, does not provide information about the strength of the association. Unlike significance tests, effect size is independent of sample size and can help to understand the magnitude of differences found. Odds ratios measure how many times bigger the odds of one outcome is for one value of a variable compared to the other. If there is no association between two variables, then the odds ratio = 1. When the odds ratio is above or below 1, it is possible that there is a significant association. According to the literature, this odds ratio indicates a medium effect size (Chen, Cohen, & Chen, 2010). Confidence intervals provide an indication of how reliable an odds ratio is (Field, 2013). The confidence level is the probability that the confidence interval contains the true odds ratio. The wider the confidence interval the greater the uncertainty associated with the estimate. If the 95% confidence intervals do not contain the value 1, then the association is significant. The odds ratio above is bigger than one, and the confidence intervals do not contain the value 1, therefore, it suggests the result is significant. The confidence intervals here also quite narrow, therefore we can be confident that the actual OR that we report is likely to be correct and reflect the true value.

Calculating the odds ratio:

Odds (contacting GP when referred

with Positive FINDRISC and Positive HbA1c) =
$$\frac{\text{number that contacted GP}}{\text{number that didn't contact GP}}$$

$$= \frac{88}{26}$$

$$= 3.38$$

Odds (contacting GP when referred

with Positive FINDRISC & Negative HbA1c result) = $\frac{\text{number that contacted GP}}{\text{number that didn't contact GP}}$

$$= \frac{67}{67}$$

$$= 1.00$$

Odds ratio = $\frac{\text{odds}_{\text{contacting GP referred with Positive FINDRISC and Positive HbA1c result}}}{\text{odds}_{\text{contacting GP referred with Positive FINDRISC and Negative HbA1c result}}}$

$$= \frac{3.38}{1.00}$$

$$= 3.38$$

It was also calculated as a x d / b x c to check the calculation.

$$88 \times 67 / 67 \times 26 = 5896 / 1742 = 3.38$$

Discussion

The first objective of this study was to determine the uptake of dental patients using FINDRISC and HbA1c information as preliminary screening tools in screening for possible diabetes, and determine the number of patients at risk of diabetes.

As with the previous US and UK studies, the current study found that many dental patients were happy to participate and receive one or more diabetes screening tests offered to them.

The results showed that 50% of eligible patients consented to participate. The refusal rate of N=515 was, however higher than the figure stated in Wright et al. (2014). Several reasons for this can be offered, such as, that potential participants are much more likely to take part in research that is concerned with an issue which is particularly relevant to the participants' lives, overall there is a decline in willingness to participate in scientific studies in Western countries, which may hold little immediate benefit to the participant (Galea & Tracy, 2007). Participants may be wary of committing their involvement to research in an endeavor that is likely to take up a substantial amount of their time given how scientific research has become increasingly demanding over the last decade (Galea & Tracy, 2007). When attending the dental surgery for appointment, the last thing some patients want to be doing is looking at other aspects of their health when they might be nervous about their dental appointment. After reading the participant information sheet sent to them before their appointment they may have seen the detail in the information and thought that it would take up too much of their time. Finally, the number of participants who were unable to participate due to not meeting the inclusion criteria was expected due to the prevalence of diabetes and the age limit set for the study. Dental patients aged under 45 years were not eligible for the study and so a large number of patients attending the surgery could not even be approached.

In the current study, almost half of dental patients screened using the FINDRISC were found to be at significant risk of developing diabetes based on the current cut-off score of 10 that was available at the time of the study. In line with previous work, the majority of participants fell into the slightly elevated risk category, with a personalised risk score of between 7 and 11 (Costa et al., 2013). Wright et al. (2014) found that 84% of dental patients screened had at least some increased level of risk of diabetes, based on the NICE guidance tool which included a risk questionnaire and BMI measurement. The current sample, based on the risk questionnaire alone showed a similar result; that N=419 (81%) of the 520 participants had some level of elevated risk of diabetes.

The use of a FINDRISC cut off score of 10 to go on to conduct further screening test had been recommended in the literature (Tankova et al., 2011). When evaluating the performance of this test in a representative sample of high-risk Bulgarians, the ROC curve analysis indicated good performance of FINDRISC in predicting diabetes with AUC 0.708 (95% CI 0.685–0.731). For a cut-off point on FINDRISC of ≥ 12 , sensitivity was 0.78 (95% CI 0.71–0.84) and specificity was 0.62 (0.58–0.68). The ROC curves indicated good performance of

FINDRISC also in predicting both prediabetes and diabetes with AUC 0.701 (95% CI 0.672–0.731). For a cut-off point on FINDRISC of ≥ 10 , sensitivity was 0.84 (95% CI 0.71–0.90) and specificity – 0.61 (0.54–0.71). Therefore, they recommended that further laboratory testing for detecting undiagnosed prediabetes and diabetes in subjects with FINDRISC of 10 or higher. As the results in the current study showed, using this cut-off meant that almost half of those screened using FINDRIC were found to score ≥ 10 . It could be argued that this cut-off score was set too low. A more recent study assessing the performance of the FINDRISC found that the optimal cut-off point was ≥ 13 (sensitivity = 63.8%, specificity = 65.1%) (Salinero-Fort et al., 2016).

When looking at the results the point of care HbA1c measure, N=118 (45% of those taking the test) had a score of $\geq 5.7\%$ suggesting a risk of pre-diabetes and diabetes. Compared to 30% found by Herman and colleagues (Herman et al. 2015) and 40% in the participant sample of Genco and colleagues (Genco et al. 2014), the result in the current study was slightly higher, probably because only those with FINDRISC score over 10 were offered the HbA1c test. Additionally, recruitment was carried out in two separate, geographically different locations where people might have been considered a higher risk due to factors such as ethnicity. The majority of participants (94%) scoring 10 or higher on the FINDRISC were happy to have their HbA1c measured by the researcher. Therefore, these results support the notion that dental patients are happy to be screened for diabetes using a combination of a simple questionnaire and a more invasive finger-prick blood test.

When screening with a self-report risk questionnaire, over half of participating dental patients were found to be at risk of developing diabetes when using a cut-off score of 10. The majority of participants scoring 10 or higher on the FINDRISC were then happy to have their HbA1c measured by the researcher for further screening too, with only 17 out of 259 refusing the blood screening test. When screened using the instant HbA1c measure, of the 242 participants having their blood screened, N=54 (22.4%) were found to be at risk of developing diabetes when using a cut-off of 6.0%. In an acute-care setting, an HbA1c of 5.7% was the optimal screening cut-off for prediabetes, and 6.0% was the optimal screening cut-off for diabetes (Silverman et al., 2011). These findings were very similar to a number of previous studies in which individuals from different ethnic and racial groups and geographic regions were tested in outpatient settings. The findings that indicated an HbA1c of 6.0% as the optimal diabetes-screening cut-off were consistent with data from other studies that use

the finger prick blood samples or OGTT to define diabetes (Ginde, Cagliero, Nathan, & Camargo, 2008; Mohan et al., 2010). The diabetes-screening cut-off that these previous studies identified is lower than the diagnostic mark of 6.5% that the ADA guidelines recommend. The difference in cut-offs can be explained in part by the desired outcome of a diabetes screening test to miss fewer people with diabetes, and, therefore, screening cut-offs typically are lower than diagnostic cut-offs. When the current study was approved by the Ethics committee, they dictated that these cut-off scores be used due to current published literature, expertise, and a lack of definitive cut-offs at that time.

A recent study testing the utility of the HbA1c when used as a screening tool in pregnancy for gestational diabetes found that pregnant women with an HbA1c of $\geq 5.4\%$ showed sensitivity of 61% and specificity of 68% and sensitivity of 27% and specificity of 95% when using HbA1c cut-off value of 5.4%. They concluded that those with an HbA1c of $\geq 5.4\%$ should proceed with an OGTT (Khalafallah et al., 2016). This should then result in a significant reduction in the burden of testing on both patients and testing facility staff and resources. On the other hand, another recent study evaluated the diagnostic value of HbA1c measurements in screening of diabetes and prediabetes, and determine the cut-off point of HbA1c in a Chinese population (Liu et al., 2016). The results suggested an optimal HbA1c cut-off point of 6.3% in screening diabetes, consistent with a previous study, the authors also proposed an ideal HbA1c cut-off point of 5.8% in screening prediabetes. The findings from these recent studies suggest that there is not a definitive agreed cut-off for screening for diabetes. The result of the current study may well have been different if these other suggested cut-offs had been used. However, because the aim of the study was to screen for risk of diabetes in an otherwise unknown risk population and then recommend further diagnostic testing by their GP in those patients scoring above the cut-offs, the cut-offs used in this study were deemed satisfactory.

In terms of the study limitations, there was a discrepancy in the numbers of patients who were eligible to participate and those that did consent not only because there were patients who refused to participate, but because the method of data collection meant that some patients who were eligible to participate were missed because the researcher was not able to approach them before their appointment with the dentist. Therefore, the number of dental patients who would have participated might be different. If the study were to be replicated,

ideally, the study would have more than one researcher working on the study approaching participants, recruiting patients and assessing risk and screening.

A strength of the study could have also been a limitation where the researcher had an awareness of risk communication and used systematic review-informed ways to communicate risk. Existing staff at the dental practices may not have had this background which limits the ecological validity of the work. Other dental practices would need their existing staff trained on how to deliver the risk communication.

The other aim of the current study was to explore whether those participants who were advised to see their GP for a diagnostic test following an increased risk result from the screening measures, followed the recommendation to do so. More specifically, was there a difference in follow-up GP rates between those referred to their GP with just one increased risk result (positive FINDRISC) and those with two risk results (positive FINDRISC and positive A1c result).

Results showed a high proportion (59.85%) of those advised to visit their GP for further formal diabetes testing followed this advice and contacted their GP regardless of screening method. This is a much more promising result than found previously. For instance, Wright et al. (2014) reported that only 20% of patients identified as at risk of developing diabetes attended their GP. Genco et al. (2014) reported that 35% attended their GP for follow up; though there was a significant difference in follow-up rates between patients referred from a community health centre where over 78% attended their GP compared to only 21% from private dental offices. The higher follow-up rate in the current study could be attributed to the detail of the risk communication given to patients. Individualised risk communication is known to be more effective than generalised risk communication at increasing screening participation (Bould, Daly, Dunne, Scott, & Asimakopoulou, 2016; Edwards et al., 2013).

The number of positive risk scores significantly influenced GP contact; patients were more likely to contact their GP if they had received two positive risk scores. The odds ratio of patients contacting the GP was 3.38 times higher if they were referred with two positive risk results (both a positive FINDRISC and positive HbA1c risk result) as opposed to just one (a positive FINDRISC but negative or no HbA1c risk result).

Screening failures occur not only from a lack of screening but also from breakdowns in follow-up on positive tests, which hinder the benefits of screening (Green et al., 2014). There are several reasons why dental patients in the current study did not follow up their positive screening tests with a follow up at their GP. The colorectal cancer literature has found that the general public have a preference for non-invasive screening tests (Benning, Dellaert, Severens, & Dirksen, 2014) and that having a choice of test would have the greatest impact on screening participation (Marshall et al., 2007). In the current study, having two positive screening tests, one non-invasive and one invasive, might have made participants feel more susceptible to diabetes so they contacted their GP. On the other hand, having a positive FINDRISC result followed by a negative HbA1c result might have led to confusion in some participants, making them unsure of what to think and whether to contact their GP for follow-up. Conversely, the negative HbA1c result may have taken precedent over the positive FINDRISC result if it was seen as more reliable being an invasive test, therefore not being motivated to contact their GP. There may have also been a tendency to consider diabetes as lacking in severity and being easily controllable leading to participants not contacting their GP. Previous studies have argued this perception to be more pronounced in the screening context, which aims to identify diabetes at an early stage and, as such, could minimise the impact of diagnosis (Eborall et al., 2007).

There are several limitations to this part of the study. Firstly, the outcome variable that was created from follow up data was simplified. Initially, the outcome of whether those asked to see their GP for a follow up diagnostic test actually received the test. However due to the complexity of the follow up data, for example, some GPs didn't feel a diagnostic test was necessary despite the patient seeing the GP for follow up, and some patients having had an appointment with their GP but awaiting the diagnostic test appointment, the outcome variable was simplified to cover all aspects of contact made with the GP. Patients were identified as having taken the advice to seek a follow up test from their GP if they had made contact with the GP which covered anything from having an appointment made, to having received a diagnostic test and the result. The problem with this outcome is that it might not have measured the component of actual behaviour; instead it may have only measured intention for some patients. Therefore, the findings should be considered with caution, that the screening tests may not have led to actual follow up behaviour, it may have led to behavioural intention. Additionally, in cases where there was no follow up data received through GP confirmation, the results relied on self-report data from the patient; they may have said they had made

contact with their GP because they had been advised to do so, and didn't want to be seen as non-compliant.

More work is needed to develop strategies to improve the follow-up at GP practices patients identified as at risk of developing diabetes therefore, behaviour change techniques could be employed here.

Conclusion

The study demonstrates a viable method of diabetes screening that shows an acceptable rate of uptake by dental patients. It also demonstrates a relatively high number of patients 'at risk' of developing diabetes being referred to their GP when using a cut-off of 10 on the FINDRISC, and still a significant number of people at risk when screening using HbA1c information.

Chapter 6

To what extent can psychological variables predict post-screening health behaviours in dental patients at risk of developing diabetes?

Introduction to chapter

The previous chapter documented the proportion of dental patients who attended their GP for diabetes diagnostic testing after being advised to do so and explored whether there was a difference in attendance behaviour according the type of risk information used to refer a patient to their GP (FINDRISC risk result vs. FINDRISC & HbA1c risk result). It is now of interest as to whether it is possible to predict what makes a person follow up the advice given to seek a diagnostic test from their GP from a set of theoretically driven psychological variables. This chapter explores the research questions set out in bold:

1. What is the most effective way to communicate individualised risk information to increase screening participation or its psychological predictors?
2. What proportion of dental patients accept an offer to be screened for type 2 diabetes in a primary care dental setting?
3. What is the risk of type 2 diabetes in primary care dental patients as assessed through self-report and physiological measures?
4. What is the effect of personalised diabetes risk communication on subsequent health behaviours?
- 5. What is the psychological profile of patients at risk of diabetes?**
- 6. To what extent do psychological variables predict post-screening further testing or health behaviours?**
7. What are patients' and dentists' views on screening for diabetes in dental settings, and can this help to further explain post-screening further testing or health behaviours?

Background

The prevention of T2D is a challenge for healthcare professionals. Screening in those at risk for developing diabetes is thought to be necessary to implement preventive measures in patients prior to the manifestation of diabetes and to subsequently diagnose the disease (Karter et al., 2007).

There is evidence to suggest that not only medical aspects, but also psychological factors, influence healthy or preventive behaviours, including the perception of risk; an individual's'

judgment of the likelihood of experiencing an adverse event (Branstrom, Kristjansson, & Ullen, 2006). Therefore, in prevention programs, communication about risk has been regarded as one of the key preventive strategies (Lavielle & Wachter, 2014). It is assumed that by receiving information, people will modify their behaviour to reduce their risk (Cook & Bellis, 2001). Specifically, this means that at the moment of making a decision concerning a specific behaviour, individuals will adhere to the basic principles of a rational choice, including understanding the received information, weighing its importance and making a decision that will optimise the expected value of the outcome (Lavielle & Wachter, 2014). However, evidence has demonstrated that people often fail to weigh the information; rather, their decision model is often intuitive, where individuals evaluate the consequences differently, according to their own values and priorities (Eiser, 1998). Therefore, even though knowing about risks is a first step for people to adopt and maintain behavioural changes other factors are involved in this process. In this sense, the relationship between knowing the risk factors for developing a disease and the adoption of preventive behaviours cannot be regarded as causal. People may know that they are exposed to a risk factor, but unless they perceive that some personal aspect is under threat, people often do not perceive themselves as being susceptible (Tate et al., 2003). As such, perceived risk is an essential component of the majority of models of health behaviour.

It is unknown if diabetes risk perception can influence health behaviours aimed at reducing the risk of diabetes (Walker et al., 2007). Therefore, Lavielle and Wachter (2014) assessed the role that risk perception can play on health behaviours, and determined if risk perception influences an individual's behaviour for preventing T2D, specifically glucose screening. Eight hundred interviews were conducted in Mexico, stratified by socioeconomic level. The perception of risk of developing diabetes, family history, health status and socioeconomic variables were evaluated, and also their association with glucose screening frequency. Results showed that risk perception was significantly associated with the frequency of blood glucose screening. Having a first-degree relative with diabetes, being older than 45 years and belonging to a middle socioeconomic level increased the probability of participants seeing a health professional for glucose screening. The authors concluded that blood glucose screening is a complex behaviour that involves a person's perception of threat, defined as feeling vulnerable to the development of diabetes, which is determined by the person's environment and their previous experience with diabetes.

Effective risk communication depends not only on presenting general risk factors and preventive information but also on factors unique to the individual. Acceptance of a risk message depends on an individual's knowledge, values, and beliefs (Berry, 2004).

Personalised interventions in which the message is based on an individual's beliefs about a disease, personal risk factors, and knowledge of the effectiveness of screening for a particular disease may be viewed as more salient and lead to the desired behaviour (Birmingham et al., 2015; Noar, Benac, & Harris, 2007).

Theory-based interventions addressing multiple determinants of behaviour are believed to have the highest likelihood of promoting healthy behaviours such as screening (Briss et al., 2004). To maximise screening success, it is important to understand why some individuals fail to use screening services. Mood, and in particular low mood (e.g. depression) has been shown to be a reliable predictor of screening attendance (Burton, Waddell, Tillotson, & Summerton, 1999). Social cognition models have also been used to understand and predict health-related behaviours such as adherence to screening (Boonyasiriwat et al., 2014b).

One such model is the Extended Parallel Process Model (EPPM), which incorporates affective processes, such as fear, in risk communication (Witte, 1994) and derived from the Protection Motivation Theory (Rogers, 1983). The EPPM focuses on channelling fear in a protective direction rather than a maladaptive direction. The model is based on the idea that when individuals fear a threat, they will be motivated to take action to reduce the unpleasant state. Fear can then be reduced by adaptive actions to control the danger or by maladaptive actions to control the fear. The model posits that when an individual is presented with a fear-arousing message two cognitive appraisal processes will be initiated: (1) threat appraisal and (2) efficacy appraisal. In the first appraisal, the individual considers two aspects of the perceived threat: severity and susceptibility. Severity appraisals involve determining the degree of harm expected from the threat (e.g., 'Diabetes could kill me.'), while susceptibility appraisals involve determining how likely the threat could affect the individual (e.g. 'I have a family history of diabetes so I can get this disease.'). If the perceived threat is determined to be low, the individual is unlikely to process the message further. However, if the perceived threat is high, the individual will enter the efficacy appraisal stage to evaluate response efficacy and self-efficacy (Birmingham et al., 2015). In response, efficacy of the individual assesses how effective the recommended behaviour will be in averting the threat. ('A blood glucose test could detect diabetes early and reduce my risk of severe diabetes related

complications.’). In self-efficacy, the individual assesses their ability to perform the recommended behaviour to avert the threat (‘I am capable of getting a blood glucose test’). When both threat and efficacy appraisals are high, the individual will enter a cognitive process to control the danger and will engage in adaptive behaviour (e.g., undergoing a blood glucose test). If threat appraisals are high but efficacy is low, the individual will enter a cognitive process to control the fear rather than the danger. This process is likely to lead to maladaptive responses such as defensive avoidance (e.g., ‘I’m not going to think about that!’) (Birmingham et al., 2015; Grasso & Bell, 2015).

When a message creates a high perceived threat but the perceived response efficacy remains low, fear control processes are engaged and will dominate a person's behaviour, resulting in message rejection, denial, or minimization. However, when a message creates high perceived threat and the perceived response efficacy is also high, danger control processes are engaged and will dominate a person's behaviour, resulting in message acceptance and attitude, intention, and behavioural changes. Thus, a person involved in danger control responds to the danger and not to his or her fear. The EPPM explains both emotional (fear control) and cognitive (danger control) reactions to fear appeals and it describes the conditions most likely to produce certain attitudinal or behavioural responses.

Although other models, such as Protection Motivation Theory, Health Belief model etc. also consider threats as a means to behaviour change, EPPM is a particularly sound model to use in screening studies. For example, previous studies have examined the EPPM in relation to early detection behaviours such as testicular self-exam (Morman, 2000), mammography (Hubbell, 2006), skin cancer screening, and sun protective behaviours (Cho & Salmon, 2006). These previous studies suggest that the approach of promoting high threat and high efficacy may be effective in public health campaigns. Fear appeals which generate perceptions of threat and fear, as well as high levels of efficacy, have resulted in significant behavioural changes. A further study examined the fear control/danger control responses that are predicted by the EPPM (Gore & Bracken, 2005). In a campaign designed to inform students about the symptoms and dangers of meningitis, participants were given either a high-threat/no-efficacy or high-efficacy/no-threat health risk message to test the extreme assumptions of the EPPM. The study supported the main predictions of the EPPM in the context of another health concern; meningitis, however, the results also provided new evidence that only a marginal amount of threat in a health risk message is needed to move the

target audience toward the anticipated protective measures. In addition, the results suggested that messages which contain only threat may scare the target audience further into fear control (Gore & Bracken, 2005). Nevertheless, there was a lack of follow-up data collected in the study to see if participants received the meningitis vaccine; the researchers instead anonymously tracked vaccine inquiries to act as the post-test measure.

Little is known about how the EPPM may be used to explain post-diabetes screening or testing intention\ and behaviour. Glucose screening is said to be a complex behaviour that involves the person's perception of threat, defined as feeling vulnerable to the development of diabetes, which is determined by their environment and their previous experience with diabetes (Lavielle & Wachter, 2014).

In the context of diabetes screening, receiving a positive result on the FINDRISC (and therefore being identified as 'at risk' for having diabetes) and having a high HbA1c reading, can be conceived as threat information. Visiting the GP to receive the FGBT and/or OGTT is considered the adaptive response and failing to visit the GP is considered to be the maladaptive response. As such, the EPPM may be a useful theoretical model to understand uptake of diabetes screening following a positive test result on the FINDRISC and in turn may be used to develop methods to ensure maximum uptake. At present however, these hypothesised psychological factors underpinning attendance at a diabetes screening test have not been researched.

When predicting future health behaviour, it is important that researchers are clear what variables predict any particular outcome, to include extraneous variables. Research has proposed that socio-demographic factors (e.g. age, marital status, education, income, and race), family history (e.g., family or personal history of chronic diseases), healthcare utilisation (e.g. health insurance coverage, regular contact with GP), awareness factors (e.g. knowledge of and attitude towards screening, perceived risk of developing a disease), past screening behaviour (e.g., mammography, pap smear, prostate cancer screening), and lifestyle (e.g. history of smoking, alcohol intake, and physical activity) may individually or in combination affect screening behaviours (Hategekimana & Karamouzian, 2016).

Mental health disorders may also influence screening participation (Calderwood et al., 2013). Mental health patients have an increased rate of morbidity and mortality (Colton &

Manderscheid, 2006). For example, mental health conditions have been associated with lower mammography rates (Egede, Grubaugh, & Ellis, 2010), pap smears (Leiferman & Pheley, 2006), and cholesterol testing (Lord, Malone, & Mitchell, 2010). This might mean that mental health conditions might serve as a potential barrier to health screening due to greater difficulties in adhering to behaviours related to long-term health goals or larger emphasis put on the management of the mental health condition compared to seeking preventive healthcare (Katon, 2003). Depression is one such variable that is known to interfere with risk information processing (Hammen & Zupan, 1984) and its influence on self-reports should be assessed in any work seeking to predict future behaviours.

This study used EPPM as a theoretical model to explore the psychological variables that might have guided our sample of dental patients to undertake post-screening health behaviours. In particular, the study set out to address the following research questions:

5. What is the psychological profile of patients at risk of diabetes?
6. To what extent do psychological variables predict post-screening further testing or health behaviours?

Method

The study methods are described in detail in chapter 4. Briefly, participants who were found to be at risk of developing diabetes from the screening measures conducted, completed questionnaires to assess mood using the CES-D scale, and a further questionnaire measuring EPPM variables through asking participants about their views on diabetes and screening. The psychological measures were assessed for internal consistency. Cronbach's alpha was performed on the CES-D scale and each of the subscales on the EPPM measure. Cronbach's Alpha could not be calculated for the EPPM Severity subscale as this subscale only had one item. Table 5 below reports Cronbach's α for each scale and subscale calculated.

Table 7 - Cronbach's alpha for CES-D and EPPM subscales

Scale or Subscale	α
CES-D measure	.85
EPPM Self-efficacy	.81
EPPM Intention	.68

EPPM Response efficacy	.88
EPPM Rewards for maladaptive response	.61
EPPM Fear	.93
EPPM Response costs	.87
EPPM Vulnerability	.87
Overall EPPM measure	.81

Usual Cronbach's alpha criteria were used to assess the data above (Kline, 1999). On the basis of these, the CES-D scale was found to have high internal consistency, with a Cronbach's $\alpha = .85$. EPPM subscales varied in levels of internal consistency. Self-efficacy, response efficacy, response costs, vulnerability and fear had high reliabilities, as all Cronbach's α values were greater than .80. The intention subscale and rewards for maladaptive response subscale had lower reliabilities with Cronbach's $\alpha = .68$ and $\alpha = .61$, respectively. Whilst these are just below the ideal cut-off point of .7, it is argued that values below this cut-off can realistically be expected because of the diversity of the constructs being measured (Kline, 1999). Additionally, whilst this questionnaire measure was created for the purpose of this study, it has also been suggested that in the early stages of research, values as low as .5 will suffice (Nunnally, 1978).

Results

The data collected are present by the respective research question that they each answer. These follow in the sections below.

Research question 5

What is the psychological profile of patients at risk of diabetes?

It was of interest to look at the psychological profile of patients who were found to be at risk of developing diabetes from the screening measures conducted. The EPPM scale measures several constructs; severity, fear, self-efficacy, response efficacy, response costs, vulnerability, rewards for maladaptive response and intention. The overall scale range is 1 to 136. The fear subscale range is 1 to 16, where a higher score represents greater fear towards diabetes. The vulnerability subscale range is 1 to 10, where a higher score represents a greater feeling of vulnerability towards diabetes. The intention subscale range is 1 to 10, where a higher score represents more intention to have a diabetes diagnostic test. The response costs

subscale ranges from 1 to 40, where a higher score represents a greater belief in the potential costs to of receiving a diabetes diagnostic test to an individual. The severity subscale range is 1-5, where a higher score represents the belief that diabetes is a severe condition. The rewards for maladaptive response subscale range is 1-10, where a higher score represents the belief that there is a greater reward for a maladaptive response to a diabetes diagnostic test. The response efficacy subscale range is 1 to 25, where a low score represents a person's belief in the efficacy of a diabetes diagnostic test. The self-efficacy subscale range is 1 to 20, where a higher score represents a persons' self-confidence to have a diabetes diagnostic test. The CES-D scale measures the presence of significant mild depression. The scale uses a cut-off score of 16, whereby a score of 16 or higher is indicative of significant mild depression. Scores can range from 0 to 60.

Table 8 - Mean and SDs for psychological variables in patients at risk of diabetes, T values and P values for each psychological variable by level of contact made with GP; that being some contact or no contact.

		Mean	SD	t	P
CES-D score	All at risk patients	13.20	9.20		
	No contact with GP (N=80)	12.31	9.64	-1.15	.25
	Some contact with GP (N=138)	13.81	9.10		
EPPM Severity	All at risk patients	4.67	.64		
	No contact with GP (N=84)	4.63	.71	-1.02	.31
	Some contact with GP (N=147)	4.71	.52		
EPPM Vulnerability	All at risk patients	6.05	1.58		
	No contact with GP (N=83)	4.97	1.33	-9.10	<.01
	Some contact with GP	6.66	1.37		

	(N=147)				
EPPM Rewards for Maladaptive response	All at risk patients	5.94	1.84		
	No contact with GP (N=82)	6.04	1.84	.41	.68
	Some contact with GP (N=147)	5.93	1.83		
EPPM Response Efficacy	All at risk patients	8.91	3.33		
	No contact with GP (N=84)	8.83	3.38	-.60	.55
	Some contact with GP (N=148)	9.08	3.32		
EPPM Self-efficacy	All at risk patients	16.47	3.07		
	No contact with GP (N=82)	16.43	3.25	.14	.89
	Some contact with GP (N=147)	16.37	2.98		
EPPM Response costs	All at risk patients	15.42	5.27		
	No contact with GP (N=83)	15.13	5.38	-.67	.51
	Some contact with GP (N=143)	15.60	4.94		
EPPM Intention	All at risk patients	8.23	1.61		
	No contact with GP (N=84)	8.39	1.59	1.19	.24
	Some contact with GP (N=146)	8.13	1.62		
EPPM Fear	All at risk patients	8.20	2.96		

	No contact with GP (N=83)	7.46	2.65	-2.66	<.01
	Some contact with GP (N=143)	8.53	3.07		

Table 8 above shows the mean scores of the psychological variables measured. The mean CES-D score was 13.2; that was below the cut-off of 16 which indicates mild depression. Therefore, those at risk of diabetes did not have a score indicative of significant mild clinical depression. No patient with a score over 16 were excluded from the analysis.

When independent samples t-tests were conducted to compare the psychological variables in high risk patients who did and those who did not contact their GP for further diagnostic tests, there was no significant difference between those patients who made contact with their GP and those that did not with regards to CES-D score ($t(216) = -1.15, p > .05$). This meant that there was no significant difference in whether patients were depressed based on CES-D scores between those that made contact with their GP and those that did not regarding follow-up to the screening measures carried out.

Mean scores for each EPPM subscale are also displayed in the table. All patients seemed to believe that diabetes was severe, with a mean severity score of 4.67 out of a maximum score of 5. There was no significant difference in severity scores between patients who did make contact with their GP and those who did not ($t(229) = -1.02, > .05$).

Patients mean score for rewards for maladaptive response, meaning the reward for not having a diagnostic test, was 5.94 out of 10. There was no significant difference in rewards for maladaptive response scores between patients who did make contact with their GP and those who did not ($t(227) = .414, > .05$).

Patients' response efficacy mean score was 8.91 out of 25; where the lower the score, the more efficacious they thought having a diagnostic test would be. There was no significant difference in response efficacy scores between patients who did make contact with their GP and those who did not ($t(230) = -.54, > .05$).

Mean intention score was 8.23 out of 10, suggesting that most participants intended to have a diagnostic test as advised. There was no significant difference in intention scores between patients who did make contact with their GP and those who did not ($t(228) = 1.19, >.05$).

Mean fear score for patients was 8.20 out of 16, suggesting that patients felt some level of fear at the thought of having diabetes. There was a significant difference in fear scores between patients who did make contact with their GP and those who did not ($t(229) = -2.66, <.01$). Those who made contact with their GP were significantly more fearful of diabetes than those who did not make contact with their GP.

Mean score for response costs was 15.42 out of 40, suggesting that on average, patients didn't view great potential cost to having a diagnostic test. There was no significant difference in response costs scores between patients who did make contact with their GP and those who did not ($t(224) = -.67, >.05$).

The mean score for self-efficacy was 16.47 out of 20, suggesting that participants felt confident in their ability to receive a diagnostic test. There was no significant difference in self-efficacy scores between patients who did make contact with their GP and those who did not ($t(227) = .14, >.05$).

Finally, mean vulnerability score was 6.05 out of 10, suggesting that patients did report some feelings of vulnerability to diabetes. There was a significant difference in vulnerability scores between patients who did make contact with their GP and those who did not ($t(228) = -9.10, <.05$). Those who made contact with their GP felt significantly more vulnerable to diabetes than those who did not make contact with their GP.

In summary, vulnerability and fear were the only two EPPM variables which differed significantly between those who contacted their GP and those who did not. Those who made contact with their GP reported significantly higher vulnerability scores and a significantly higher fear score than those who did not make contact with their GP for a follow up diagnostic test. This meant that those people who made contact with their GP felt significantly more fearful of, and more vulnerable to diabetes than those who did not make contact with their GP regarding follow-up to the screening measures carried out.

Research question 6

To what extent do psychological variables predict post-screening further testing or health behaviours?

Table 9 shows the coefficients of the model predicting whether a patient made contact with their GP regarding a diagnostic test. The model explained 41% (Nagelkerke R^2) of the variance in GP contact.

Table 9 - Coefficients of the model predicting whether a dental patient contacted their GP following diabetes screening

<u>Variables</u>	<u>β</u>	<u>p</u>	<u>Exp(B)</u>	<u>95% C.I</u>	
				<u>Lower</u>	<u>Upper</u>
Vulnerability	.996	<.001	2.71	1.99	3.65
Fear	.150	.034	1.16	1.01	1.34
Severity	.197	.50	1.22	.69	2.16
Rewards for Maladaptive response	1.43	.21	1.14	.93	1.41
Response efficacy	.04	.53	1.04	.92	1.19
Self-efficacy	.06	.40	1.22	.92	1.06
Response costs	-.01	.85	.99	.90	1.09
Intention	-.07	.67	.93	.68	1.28
CES-D	.01	.66	1.01	.97	1.05

When the predictor variables were entered into the model, CES-D score, intention, self-efficacy, severity, response costs, response efficacy, and rewards for maladaptive response were not significant predictors of whether a dental patient made contact with their GP for a follow up diagnostic test following diabetes screening.

However, the results suggest that a high risk dental patient's fear of diabetes score and vulnerability to diabetes score were able to significantly predict whether a patient contacted their GP. This means that the more vulnerable people felt about the chance of developing diabetes in the future and the more fearful they were of the disease, the higher the chance they would make contact with the GP to arrange diagnostic testing.

The odds of a patient contacting their GP was 2.71 (95% CI [1.99,3.65]) times higher for every 1-point increase in score of vulnerability to developing diabetes. The odds of a patient contacting their GP was 1.16 (95% CI [1.01,1.34]) times higher for every 1-point increase in score of fear of developing diabetes. The odds ratios are greater than 1, therefore this suggests that fear and vulnerability was higher in those who contacted their GP. Whilst these results are statistically significant, the odds ratios are only small, and small to medium in size respectively, according to Chen et al (2010). However, small effect sizes aren't unusual in behavioural research. Confidence intervals measure the precision of an effect estimate, which here is expressed as the odds ratio. Confidence intervals are used because a research study recruits only a small sample of an overall population, so by having an upper and lower confidence limit, it is possible to infer that the true population effect lies between the two confidence intervals. Here, the 95% confidence intervals are narrow, particularly for the fear variable, which means that this is the range within which the true value is likely to lie with 95% confidence, and that our OR is likely to reflect the true value in the population.

Following the result that fear and vulnerability were able to significantly predict GP contact, these two variables were used to further explore their relationship with the number of positive risk screening tests a patient received.

Table 10 - Correlation coefficients for the relationship between the number of positive screening tests patients received and the significant predictor variables from the logistic regression

	EPPM Fear		EPPM Vulnerability	
Number of positive screening tests	Pearson's $r = .02$ N=221	P = .73	Pearson's $r = .21$ N=225	P < .05

Table 10 reports the results of a Point Biserial correlation looking at the relationship between the presence of two positive screening tests as opposed to just one, and the variables found to significantly predict GP contact in the binary logistic regression reported above.

There was a strong significant positive correlation between having two positive screening tests and EPPM vulnerability. This result suggests that those patients who received a positive risk result on both the FINDRISC screening measure and a positive risk result from the finger prick blood test felt more vulnerable to developing diabetes than those who received only a positive risk result on the FINDRISC screening measure, in other words, as the number of positive screening tests increased from one to two tests, vulnerability toward diabetes scores increased. There was a weak, non-significant positive correlation between having two positive screening tests and EPPM fear. This result suggests that those patients who received a positive risk result on both screening tests did not feel significantly more fearful of diabetes than those who received just one positive risk screening result, in other words, fear of diabetes did not significantly increase when the number of positive screening tests increased from one to two tests.

Summary of results

The data suggested that patients found to be at risk of diabetes did not report scores indicative of significant clinical depression, but did report the belief that diabetes was a severe condition, reported a high level of intention to receive a diagnostic test, and reported feeling some level of fear and vulnerability to diabetes. Fear of diabetes score and vulnerability to diabetes score were able to significantly predict whether a patient contacted their GP for a diagnostic test; albeit with small effect sizes. Finally, of these two significant predictors, vulnerability was significantly correlated with having received two positive screening tests as opposed to just one. These results are discussed next.

Discussion

The aim of this study was to predict what makes a person follow up the advice given to seek a diagnostic test from their GP from a set of theoretically driven psychological variables. Risk communication involves raising awareness of increased diabetes risk and creating a sense of efficacy. The EPPM contains both components and has been effectively used across a variety of topics such as cancer screening, and sun protection behaviour but had not previously been examined in the context of diabetes diagnostic testing and behaviour following diabetes screening. Hence, this research question was set and the results from the binary logistic regression showed that both fear and vulnerability were able to significantly predict whether a patient found to be at risk from the screening measures would contact their

GP. When a Pearson's correlation was conducted to look into this further, a relationship was found between the number of positive risk screening tests and vulnerability to diabetes. Those patients who received a positive risk result on both the FINDRISC measure and the finger prick blood test felt significantly more vulnerable to developing diabetes than those who received a positive risk result on the FINDRISC measure alone. None of the other EPPM components were found to be able to significantly predict whether a patient found to be at risk from screening would contact their GP; as well as no statistical significance, those EPPM components also had very small effect sizes, therefore having little or no impact on the decision to seek a diagnostic test from the GP.

The findings in the current study can be compared and contrasted to previous work assessing the predictors of screening. Recently, Leung and colleagues conducted a study which aimed to describe the prevalence of CRC screening and examine the risk factors in a Chinese population. Guided by the Health Belief Model and Extended Parallel Processing Model, 240 adults aged 60 or older were asked to complete a questionnaire which collected information on demographic variables, CRC-related psychosocial variables and whether or not they had received a CRC screening test in the past 10 years. Results of a logistic regression suggested that participants with lower perceived knowledge barriers and severity-fear (severity relating to mental status and negative effects to their current personal and family lives) were significantly associated with participation in CRC screening (Leung, Wong, & Chan, 2016). But there were no significant associations between cancer fear and screening, as seen in the current study. The insignificant result of fear on CRC screening was contradictory to findings from the review on older adults which had showed that fear may either be a facilitator of, or a barrier to participation (Guessous et al., 2010). Another recent study looking at the factors associated with prostate cancer screening behaviour through a self-report questionnaire assessing screening behaviour cancer in Iranian men found that knowledge and perceived threat consequences of prostate cancer were psychological predictors of prostate cancer screening behaviours among men over 50 years of age (Barati et al., 2016). Whilst knowledge and perceived threat weren't directly measured in the current study, they are variables that are important to screening uptake and can be associated with other EPPM components.

Guided by the EPPM, Birmingham et al. (2015) examined the impact of a personalised, remote risk communication intervention on behavioural intention and colonoscopy uptake in

relatives of CRC patients, assessing the original additive EPPM model and an alternative model in which each theoretical construct contributed uniquely. The intervention involved participants receiving tailored print materials and a cancer risk assessment and counselling telephone call by a genetic counsellor. Screening intentions and actual screening behaviour verified through medical records were measured. Results from structural equation modelling showed there to be a poor main model fit where an additive relationship exists between perceived severity and susceptibility (i.e., threat) and between perceived response and self-efficacy (i.e., efficacy). When an alternative model was used in which perceived susceptibility, severity, self-efficacy, and response efficacy each contribute individually to the model, perceived susceptibility was significantly associated with intention to screen while perceptions of CRC severity were not. Additionally, perceived self-efficacy but not perceived response efficacy was significantly associated with intention to screen.

According to the EPPM, self-efficacy may be viewed as the degree to which the individual perceives he or she can perform the recommended response to avert the threat. In the case of diabetes and for the purposes of our study, self-efficacy is the degree to which the individual perceives he or she is capable of obtaining a diagnostic test, and response efficacy is the degree to which the individual believes that the diagnostic test can early-detect and prevent diabetes. In fear-arousing communications aimed to increase health-promoting lifestyle choices, self-efficacy is often associated with the self-control, self-regulation, and self-motivation needed to perform the behaviour. However, many of these health-promoting lifestyle behaviours need to be performed on a regular basis, while diabetes screening need be performed less regularly. Whilst, self-efficacy would include the self-motivation to actively seek a diagnostic test following the recommendation to do so, it also involves being able to get an appointment to get the test done, and any other barriers that might exist such as problems with transportation and time for example. Therefore, while one may strongly agree that a diagnostic test can detect diabetes and reduce the risk of diabetes related complications through early detection, without the ability to get the diagnostic test done, belief in the effectiveness of diagnostic testing would not likely predict GP contact. Therefore, barriers to getting a diagnostic test must be overcome in messages to increase efficacy.

The finding from the current study that increased fear of diabetes was a significant predictor of GP contact is notable. This result is consistent with a finding that increased apprehension about developing breast cancer is a modest but reliable predictor of increased likelihood to

get screened (Hay, McCaul, & Magnan, 2006). Guided by the EPPM, another study examined cognitive, affective, social, and behavioural predictors of intention to undergo colonoscopy screening in individuals with a family history of CRC (Boonyasiriwat et al., 2014a). Relatives of colorectal cancer cases eligible for colonoscopy screening completed a survey assessing constructs from several theoretical frameworks. Results suggested that perceived CRC risk, past colonoscopy, fear of CRC, support from family and friends, and health-care provider recommendation were determinants of colonoscopy intention in the next six months. Whilst their study did not assess actual colonoscopy uptake, even though readiness for colorectal screening is a predictor of future behaviour, intention to screen was determined by fear of CRC; like fear of diabetes was predictive of GP contact in the current study. In practice, these findings here suggest that, if a patient is not fearful of diabetes, they are less likely to contact their GP; thus making the communication of diabetes risk in the dental setting important if the aim is to increase GP contact following positive diabetes screening results. If there is fear of diabetes following risk communication, then there is an increased chance that a person will contact their GP for further testing. The same can be said for vulnerability to diabetes; if a patient does not feel vulnerable to diabetes following screening tests and the communication of their risk, they are less likely to contact their GP. If there is a feeling of vulnerability to diabetes following risk communication, then there is a greater chance that a person will contact their GP for further testing. Therefore, it is important that the person in the dental setting delivering the risk communication does so effectively to convey a certain level of fear and vulnerability to diabetes. Whilst fear and vulnerability showed statistical significance, they only had small effects. Therefore, whilst these findings show that these two components of the EPPM might be important in the decision to make contact with the GP, they may only be slightly relevant, and they certainly do not fully explain the reasons why those making contact with their GP did so. This suggests that the EPPM variables are not always able to predict health behaviour, particularly in this case. In this study, the two significant predictors were only slightly associated with the outcome, and so this leads us to question what else might be causing an increase in the behavioural outcome. Research has now for a long time looked at factors beyond demographics and a lot of research has benefitted from the use of behavioural theories and models (Askelson et al., 2015). Perhaps in this case, looking at psychological predictors of making GP contact is not the right way to investigate. This study does not lend much support to EPPM, and is not clear what it is that makes these dental patients at risk of diabetes actually make contact with their GP regarding a diagnostic test. Therefore, variables other than psychological factors might

have been able to explain GP contact, but these variables weren't studied in this research. Recent research in other areas of screening uptake has suggested that other variables can lead to the uptake of health screening such as, family income (Marmara, Marmara, & Hubbard, 2017) in breast cancer screening and age, education and smoking status in cervical cancer screening (Chang et al., 2017). However, diabetes screening studies have found that patient characteristics can influence attendance too (Christensen, Sandbaek, Lauritzen, & Borch-Johnsen, 2004). The UK ADDITION study also found that male participants and those with a higher BMI were associated with lower attendance for testing. They also found that older age, prescription of antihypertensive medication, and a higher risk score were associated with higher attendance diagnostic tests (Sargeant et al., 2010). Whilst the current study measured demographic details and patient characteristics, these details were not used in the regression model. The reason for this was that whilst individual differences are known to exist in health behaviours, some are attributable to sociodemographic factors such as gender, and are not open to change, whilst others which are attributable to social cognitive variables, such as self-efficacy or fear, are more amenable to change. Hence, why variables from a SCM model, in this case the EPPM, were considered to see if it was possible to predict how individuals would react when confronted with fear inducing stimuli. This however, might not be the case in the current study. It might be that factors which cannot be changed are what predicts GP contact following diabetes risk screening. Even if these variables might be psychological variables such as severity, it might not be possible to change this factor in an individual, therefore, it is not able to predict the outcome.

The current study did not find that intention predicted actual behaviour; intention to get a diabetes diagnostic test was not a predictor of GP contact. This result does not support the finding from Birmingham et al. (2015) whose results indicated that motivation to screen was significantly associated with colonoscopy uptake. However, the result from the current study is similar to previous research which has suggested that people with positive intentions often fail to actually perform the behaviour (Webb & Sheeran, 2006).

According to the tenets of the EPPM, when one is exposed to a fear-appeal message, an appraisal of the message's threat is first performed and then an appraisal of the individual's ability to prevent the threat. The results from the EPPM measure in the current study showed that most participants viewed diabetes as severe with little variability in perceived severity scores between those who did contact and those who did not contact their GP. Such high

severity scores create a ceiling effect that may affect the threat component of the theory. This might have contributed to the finding that severity of diabetes did not significantly predict GP contact following the screening tests. Thus, fear-arousing diabetes related messages need to focus on increasing levels of personal susceptibility which was done in the current study and which seemed to raise levels of perceived vulnerability to diabetes, particularly in those who received both a positive risk FINDRISC result and a positive risk finger prick blood test result.

Mental health disorders such as depression are said to have the potential to influence screening participation (Calderwood et al., 2013). The mean score on the CES-D measure which screens for the presence of possible depression in the participant sample was below the cut-off for significant mild depression in those at risk of diabetes. This might be why in the current study, CES-D score was not a significant predictor of GP contact as there was no significant difference in CES-D scores between those making contact with GP and those not making contact. Diabetes is one of many medical conditions that appear to be adversely affected by comorbid depression (Andreoulakis, Hyphantis, Kandylis, & Iacovides, 2012). Numerous reports have indicated that patients with diabetes are 1.5–2 times more likely to have depression compared with people without diabetes (Brown, Majumdar, Newman, & Johnson, 2005). Onset of depression may result in increased weight gain as a result of the disorder or in relation to antidepressant medication, and decreased self-care behaviours such as exercise. Also, people with depression are more likely to abuse alcohol and smoke cigarettes compared to those without depression. These behaviours can potentially increase the risk of developing T2D. Comorbid depression in diabetes has been suggested as one of the possible causes of an inadequate glycaemic control, and the presence of depression seems to impact on the short-term control of T2D (Papelbaum et al., 2011). Therefore, while the mean CES-D score was below the cut-off for the presence of depression in the current study sample, it does not mean that there was a total absence of depression in those at risk of developing diabetes. Given that diabetes and depression are closely related, this finding might not have been expected; depression might have been expected to have been more prevalent in the study sample. However, the current study only screened for possible diabetes risk, and did not diagnose diabetes in participants. Given the nature that screening will identify more than just those who actually have the condition being screened for, the majority of participants screened as at risk of developing diabetes in this study likely did not have diabetes. Therefore, there was not necessarily a greater possibility of finding depression in the sample.

The study in this chapter is not without its limitations. Whilst the CES-D measure had a strong Cronbach's alpha, not all subscales on the EPPM measure showed high reliabilities. Intention and rewards for maladaptive response subscales did not reach the desired .7 Cronbach's alpha. Whilst not a limitation, the reliability of the severity subscale was not measured as it is not possible to calculate Cronbach's alpha for single-item subscales. However, it might be possible to assess the items reliability through the test-retest approach in future. Nevertheless, the EPPM measure was created for the purpose of this study, and it has previously been said that in the early stages of research, values as low as .5 will suffice (Nunnally, 1978). On the other hand, the other subscales from the EPPM measure all exceeded the .7 Cronbach's alpha level. In addition to this, the EPPM measure relied on self-reported information, however, self-report measures are a necessary tool for behavioural research. Some of problems associated with self-report measures such as response bias, different interpretations of the rating scales for questions, understanding and honesty can be countered through the careful design and application of self-report measures. For example, response bias can be removed by 'reversing' half the questions on a questionnaire so that the variable is scored by positive responses on half the questions and negative responses on the other half, thus cancelling out any response bias (Hoskin, 2012)

Birmingham et al. (2015) suggested that that the EPPM alternative model in which each component of the EPPM contributes individually was a better fit for motivating CRC screening intentions and CRC screening behaviour, and therefore there is no clear agreement on which model best predicts cancer screening behaviours. Whilst the current study has provided an examination of how the EPPM framework may aid in interventions to motivate diabetes testing behaviour, the current study might also suggest that the EPPM model might not be a good fit when it comes to predicting diabetes diagnostic testing, and that the wrong predictors are being considered. Thus, other models for predicting behaviour should be examined to look at the determinants of diabetes screening and testing. It would also be helpful to examine the pathways between the EPPM components within the nature of diabetes screening and testing. The number of EPPM components that did not have an effect on GP contact may mean that the EPPM model may not be a useful tool to use when trying to predict GP contact.

Another limitation to the study was how GP contact was measured. Whilst follow-up data were collected for 3 months to see if patients who were advised to seek a diagnostic test from their GP following initial screening, follow up data were complex and included several types of response, from having telephoned their GP surgery to make an appointment through to having received a diagnostic test. When collecting the follow up information, some data showed that although some patients had indeed gone to see their GP as advised, their GP had made a decision that a diagnostic test was not needed. Therefore, it was decided that as the aim of the study was to see if those asked to visit their GP actually did so, the outcome variable for the study would be adapted to be whether a participant made contact with their GP or not. So whilst the outcome of whether a diagnostic test was carried out as recommended wasn't the final outcome measure, we were able to still capture more than just behavioural intention; in fact, data on actual behaviour was still collected and recorded, as the behaviour of contacting their GP as advised was measured. Additionally, the current study did more than rely solely on self-report. Final outcome data was sought from patients GP's to back up the self-reported outcome. Ideally, everyone who had been recommended to have a diagnostic test by the researcher and who did in fact contact their GP would have been given the test and their result. Additionally, ideally every participants' outcome would have been verified by the GP too at the time of follow-up data collection. However, this just cannot be guaranteed when GPs ultimately have the final say on whether to issue a patient with a diabetes diagnostic test. If they do not feel it is necessary, they won't conduct the blood test. Furthermore, those seeking a diagnostic test from their GP potentially have to attend for several appointments, from seeing their GP in the first instance, to having the blood test appointment, to then possibly having to see the GP for results follow-up. As a consequence, this can take a considerable period of time when having to consider the busy nature of GP surgeries when trying to get appointments, and an individual's own time constraints for attending appointments; thus follow-up outcome data for every participant can be difficult to obtain within a set period of time.

An important extension to this study would include determining what other factors beyond those considered in the EPPM inhibit or enhance diabetes testing behaviour. A qualitative study might therefore identify such factors and would be useful to explore an individuals' reasons for having a diagnostic test or not. The quantitative results in the current study can only explain so much of the reasons for a participants' decision to make contact with their GP or not. Whilst a person might feel significantly vulnerable to diabetes and perceive it to be a

severe enough condition to warrant following up a recommendation to receive a diagnostic test, there may still be barriers that exist which prevent a person from acting on the recommendation. A qualitative study would therefore need to explore the reasons behind the decisions made to follow-up the recommendation for a diagnostic test or not. This would certainly add valuable insight to the small effects found in the current quantitative study, and might give further ideas of factors to look at when considering predictors of GP contact.

In conclusion, the results presented in this chapter show that the more fearful and vulnerable dental patients feel towards diabetes, the more likely they are to attend post-screening diagnostic testing for diabetes at their GP surgery. Reason for attendance and non-attendance are discussed in the qualitative study that follows in chapter 8. The chapter also presents also presents dentists' views on the worth of diabetes screening at their dental surgery.

Chapter 7

What are dentists and patient's views and experiences of the on practicality and acceptability of screening for diabetes in dental settings?

Introduction

The main aim of this PhD study was to screen patients for diabetes whilst attending their routine dental appointment. In this chapter, a qualitative study is described whereby the views on the practicality and the experiences of screening for diabetes in dental settings were explored by conducting interviews with the GDPs and dental patients who took part in the screening programme.

The aim of this study was to address RQ7, the last of the research questions set in Chapter one:

7. What are patients' and dentists' views on screening for diabetes in dental settings, and can this help to further explain post-screening further testing or health behaviours?

Whilst research has already been conducted on the views of dentists and patients on diabetes screening (Greenberg et al., 2012a; Greenberg et al., 2015), the intention of the current study was to explore what dentists and their patients thought about the specific two-step diabetes screening method that they had personally recently experienced. The study is described in two parts; Part 1 focuses on views and experiences of patients who experienced the screening; Part 2 focuses on views and experiences of dentists. These are outlined below.

Part 1: Dental patients' views and experiences

Previous research has suggested that patients are willing to have a dentist conduct screening and counselling for a variety of medical conditions including diabetes (Creanor et al., 2014; Friman et al., 2015; Greenberg et al., 2012a; Sansare et al., 2015). One particular study did explore patient experiences of blood glucose screening during a secondary care periodontal visit, and found patients to be happy to receive diabetes screening in such an environment, but preferred the collection of gingival crevicular blood for testing as opposed to a finger prick blood sample being collected (Rosedale & Strauss, 2012). The intention of the current

study was to evaluate patients' views on the specific screening programme used here in primary dental care where screening test results were given almost instantaneously as opposed to a screening method used in secondary care and where blood samples were sent to the lab for analysis like in the study mentioned above (Rosedale & Strauss, 2012).

The previous chapters reported the results that dental patients welcomed the chance to be screened for diabetes when attending routine dental appointments, that over half of those patients screened for diabetes risk were in fact considered at risk of developing diabetes based on the results of the two screening tests used, and that of those patients advised to seek further diagnostic testing from their GP, the majority did in fact do so. In this chapter, the aim was to further explore these findings using qualitative methods to complement the quantitative findings to gain rich qualitative data of real life experience of being involved in a diabetes screening programme when attending a dental appointment and their thoughts on such a service, and try to further explain why patients did or did not attend the GP for follow-up diagnostic testing when it was recommended to do so.

Part 2: Dentists' views and experiences

Previous research has suggested that dentists hold a positive attitude toward diabetes screening in the dental setting (Greenberg et al., 2010). Some studies have shown the majority of dentists are willing to do such screening (Hema, Prasad, & Shetty, 2014). Trainee dentists' attitudes toward activities related to diabetes counselling, monitoring, and screening have been found to be generally positive when it comes to screening for undiagnosed diabetes; trainee dentists report that this is within the scope of dental practice (Anders, Davis, & McCall, 2014). The current study differed from previous research in that dental practitioners were interviewed in an attempt to gather rich qualitative data on their views, attitudes and experiences of diabetes screening. Additionally, the dentists who were interviewed had recently been exposed to a specific diabetes screening programme and therefore were able to comment on actual knowledge and experience as opposed to a hypothetical scenario or just the idea of screening for diabetes in the dental setting.

Methods

The methodology for this qualitative study is detailed in Chapter 4; Methods chapter. In summary, the chapter reports thematically-analysed interview data from patients who either attended or failed to attend their GP for diagnostic testing and the participating dentists.

Results

Dentist and Patient Sample

Eighteen dental patients were recruited for this qualitative part of the current study from the dental practice in Staffordshire. No dental patients were recruited from the practice in London due to the length of time since the screening programme had taken place. It was decided that recollection of experiences may not have been as accurate as the more recent experiences from dental patients at the second data collection site in Staffordshire. There were 10 females and 8 male participants. Mean age was 59.3 years. The mean FINDRISC score was 10.67, and the mean HbA1c score of those who received the test was 5.89%.

There were eight GDPs in total at the two dental practices. However, due to working hours, only six were asked to participate, all of who agreed to participate.

Of the 6 GDPs recruited; 4 were from the dental practice in Staffordshire and 2 were from the practice in South East London. Four of the dentists were male, whilst two were female; 4 of the GDPs were from a British Asian background, whilst 2 GDPs were of White ethnic background. The mean age was 40 years, and the mean length of time since qualifying was 9.3 years. All GDPs were practicing general dentistry, however, all practitioners specialised in other areas such as, cosmetic dentistry, implant dentistry and restorative dentistry.

Part one: What are dental patients' views on screening for diabetes in the dental setting?

Five themes were identified reflecting patients' thoughts about diabetes screening, and what their own individual experiences of it were in the dental setting: *knowledge and seriousness of diabetes; diabetes screening worth; changes in perception of one's susceptibility and risk; acceptability of the screening programme; reasons for GP follow-up attendance and non-attendance.*

1. Knowledge and seriousness of diabetes

Whilst the majority of dental patients were in agreement that diabetes is a serious condition, knowledge of what diabetes is, was overall quite poor.

“Diabetes is when you need to take injections every day or tablets” (Patient 5, male, low risk)

“yeah it’s from poor diet and being overweight” (Patient 9, female, high risk, GP attender)

There was some understanding of causal factors and of what treatment for the condition usually entails, but there were also some incorrect descriptions of what the condition actually is and what it involves.

“It’s to do with the pancreas isn’t it, it doesn’t work properly and you need to have insulin. I know it’s serious.” (Patient 7, female, high risk, GP attender)

“Too much sugar in your diet, too much chocolate!” (Patient 17, male, high risk, GP non-attender)

Dental patients overall had very little idea of what diabetes is, and so were unaware of how it can affect their overall health.

2. Diabetes screening worth

Dental patients seemed to acknowledge that detection of diabetes would indeed lead to better health outcomes in terms of access to treatment and management options.

“If you can catch it early enough, you can receive treatment and manage it.” (Patient 8, female, high risk, GP attender)

They acknowledged that detection would be the most important positive outcome from screening for the condition and that it could be seen as something rather routine in terms of health surveillance.

“It’s worth doing, just routinely to keep an eye on your health definitely.” (Patient 3, female, low risk)

Several patients discussed positive outcomes of screening for diabetes regardless of the result; in that if they were screened for diabetes and found to be at a low risk, then they would feel some level of reassurance from the result. Similarly, if they were found to be high risk for developing diabetes, then such knowledge would lead to further necessary investigations.

“It’s a win win sort of situation, you get screened, best case scenario, you’re all fine. Worst case, there’s something there, in which case, thank goodness you got screened so can get it checked out.” (Patient 12, male, high risk, GP attender)

“It’s good because if there’s no risk found then you can rest assured and if not then you can receive further investigation and treatment. (Patient 6, male, low risk)

However, not everyone saw such value in screening for diabetes. Some patients felt there was not much point to getting screened for diabetes as it would be picked up by a GP anyway.

“I just think my doctor would investigate if there was something he was worried about so it just seemed a bit pointless.” (Patient 18, male, high risk, GP non-attender)

3. Changes in perception of one’s susceptibility and risk

Interestingly, patients’ perceptions of their own risk of, and susceptibility to diabetes changed over the duration of the screening programme.

- Perceived susceptibility

Several patients reported feeling more or less susceptible to diabetes after receiving their risk result.

“I didn’t realise I was at such a high risk before the tests, knowing that I actually am, that was a shock.” (Patient 10, female, high risk, GP attender)

Patients described how they did not feel susceptible initially due to a lack of symptoms or risk factors that they were personally aware of, however, following the risk questionnaire and

finger prick blood test, they felt their perceived susceptibility changed after learning certain lifestyle factors would indeed increase risk of developing diabetes.

“I hadn’t realised that my waist measurement was that big and that it would have so much of an influence on my risk than it did. I definitely thought well I don’t feel ill so I can’t be diabetic.” (Patient 11, male, high risk, GP attender)

On the other hand, some patients reported feeling rather susceptible initially to the condition based on certain risk factors, and that they would have a much larger effect on their risk than they actually would. Therefore, after learning of their risk, they felt less susceptible to the condition.

“I thought I would be at a higher risk than I actually was as I’m carrying more weight than I should be at the moment, so I was pleasantly surprised and a little relieved to be honest when you said I wasn’t really at risk.” (Patient 4, male, low risk)

Here it seems that the screening result, which in this case was a low risk result, gave the patient some reassurance that their susceptibility to diabetes was not high.

- Perceived risk

As with susceptibility, several patients reported a change in perceived risk over the duration of the screening programme also. Some patients felt that following the personalised risk information, they felt more at risk of developing diabetes.

“I guess I am more at risk than I thought I was.” (Patient 13, female, high risk, GP non-attender)

On the other hand, others felt less at risk following their personalised risk result.

“I feel better knowing I’m not at a greater risk than I first thought because of the history of diabetes in the family.” (Patient 1, female, low risk)

Some patients felt that by gaining an understanding of their risk, their perceived risk changed and they were able to make an informed decision about what needed to be done following receipt of such information.

“I didn’t know that I was high risk before the screening and that the things on the questionnaire would affect my risk. I know now and that means I can go to my doctor and share my concerns now I know what affects my risk and what I need to do to improve my lifestyle like lose weight.” (Participant 12, male, high risk, GP attender)

In most cases patients recalled their risk result correctly and discussed this in light of their perceived risk. However, one particular patient misunderstood their risk information. They described how their finger prick blood screening test was within a “normal range”, and so felt at low risk, despite the risk result from the questionnaire identifying a high risk of developing diabetes. This patient saw the finger prick test as more definitive.

“Yeah I knew I didn’t have diabetes and then from your tests I am low risk because my blood test was within the normal range.” (Participant 15, female, high risk, GP non-attender)

Here it seems that the patient has disregarded the high risk questionnaire result in favour of the low risk blood test result, despite the patient still being referred for further diagnostic testing based on their high risk FINDRISC result; most likely the reason for not attending the GP for follow-up as recommended.

4. Acceptability of the screening programme

Analysis of patient experiences of the screening programme conducted identified three sub-themes; *positive aspects*; *negative aspects*; and *emotional reactions from taking part in the*

screening programme. Overall, patients described the screening programme as broadly acceptable and made some positive comments as to its usefulness and acceptability.

- *Positive aspects*

Some patients described how by receiving an invitation to take part in the screening programme, they felt it was a good idea to act on professional advice.

“When I got the letter, I thought how strange but if my dentist is asking me to go and thinks it’s a good thing then I’ll do it.” (Participant 4, male, low risk)

This participant clearly sees their dentist as a meaningful healthcare professional.

“I got a letter asking me to come for screening which was addressed from the researchers and my dentist and I thought I’d take what the professionals were suggesting.” (Participant 8, female, high risk, GP attender)

Again, similarly, another patient described that after being told their initial risk was high and that a screening blood test was recommended, they went ahead with the second blood test because they felt it was good to act on the advice of the researcher who they felt was a knowledgeable professional.

“I just thought, hey you know what you’re on about, you’re the expert, you said I need a blood test so I agreed and I just let you do the test.” Participant 12, male, high risk, GP attender)

Another patient felt that by offering the screening programme, their dentist obviously cared and was keen to take an interest in their overall health.

“I think it shows the dentist is enthusiastic and cares about my health and not just my teeth.” (Participant 6, male, low risk)

Other positive comments were made regarding the screening programme. One patient described the idea of a ‘one-stop shop’. Demanding home and work lives of people means that time is probably an issue for many people. Combining several services was seen as convenient and time saving.

“It’s like a one stop shop, everything under one roof. Get your teeth checked, see if you have diabetes. It’s a great idea!” (Participant 2, female, low risk)

Patients also commented on the thoroughness of the screening programme. Here, one patient described how having two screening tests could only be seen as a good thing.

“I liked the idea of two tests, it was very thorough, my answers to the questions let you start to see how I could be affected then the blood sample being taken let you look a little bit closer.” (Participant 7, female, high risk, GP attender)

Others felt that it was a good idea to offer this kind of service outside of the GP practice to reach out to more people and take the strain off of the GP service whose workload was already stretched without trying to encompass screening for several conditions.

“Offering this outside the GP medical practice is good as you can get more people involved with it who aren’t seeing their doctor regularly.” (Participant 3, female, low risk)

“Yeah it’s a good idea, the doctors at the surgery have enough work to contend with without checking for other illnesses so it’s good for it to be doing elsewhere.” (Participant 5, male, low risk)

- *Negative aspects*

Some patients did talk negatively about the screening programme they experienced. Negative comments tended to come from those who were found to be high risk for developing diabetes, downplaying the seriousness of their risk. For instance, patients talked about how they did not see the point of having to complete the questionnaire risk assessment if a second screening test, in this case, the finger prick blood test, was needed. They felt that that it would be better to do the more accurate test straight away.

“I didn’t really see the point of the questionnaire if I needed the blood test, why not just skip straight to that?” Participant 14, female, high risk, GP non-attender)

“Just do the test that’s more accurate in the first place I think.” (Participant 16, male, high risk, GP non-attender)

Another patient described how they did not like having two screening tests as it just allowed them to become anxious in between the first screening result and waiting for the second screening result.

“It just made me a bit anxious I think because after the first test I had to wait again knowing that you thought my risk was high and then waiting to see what the blood test was going to say.” (Participant 9, female, high risk, GP attender)

Participants seemed to undergo a process of psychological adjustment in between the two screening tests without, as their perceived risk and susceptibility changed, to, for some, being faced with the possibility of having diabetes.

- *Emotional reactions from taking part in the screening programme*

Several emotions were expressed when patients talked about their experience of taking part in the screening programme.

One patient described feeling confident following her low risk result, suggesting that screening was beneficial to her.

*“You gave me a bit of confidence in my health I think, that my risk was low.”
(Participant 2, female, low risk)*

Another described feeling relieved that after one screening test, there was no further action needed.

“Oh yes it was a relief to be told I was ok and didn’t need to have any further tests.” (Participant 1, female, low risk)

However, others described feeling of fear and worry at the thought of being at risk of diabetes.

“I did feel rather worried when you said I should see the GP. He reassured me though when I’d had the blood test and he said it was all normal and that I didn’t have diabetes.” (Participant 10, female, high risk, GP attender)

The quote below, although evidence of negative emotional reactions to the screening tests show that the nature of the step-wise screening programme used in the study enabled gradual psychological adjustment. The patient had to go through a process of readjusting their expectations of personal risk.

“I felt a bit scared at first from my score on the questionnaire but then when you said the blood test was high too, I thought to myself gosh, what if I am diabetic? I panicked a little. I was worried so went to see my doctor like you said, and having his reassurance that the next test that he did was ok, I’m fine now like.” (Participant 8, female, high risk, GP attender)

5. Reasons for GP follow-up attendance and non-attendance

Due to the nature of the screening programme, those patients who were identified as high risk for developing diabetes based on the screening tests, were advised to visit their GP for a diagnostic test. Therefore, this final theme is expressed through the following sub-themes: ‘Why I went to my GP’; and ‘Why I did not go to my GP’.

- ‘Why I went to my GP’

Often patients reported the need for reassurance and a sense of security that they knew they would get from their GP if they indeed acted upon the advice to seek a further diagnostic test.

“I wanted the reassurance from my doctor.” (Participant 11, male, high risk, GP attender)

Patients seemed to have trust in their GP to put an end to the screening programme and give them a definitive diagnostic result. They felt they needed final reassurance that they did not have diabetes.

“I wanted to see the doctor myself so I knew then I was clear.” (Participant 12, male, high risk, GP attender)

Patients also described the benefit of attending for reasons of early detection if necessary due to a lack of symptoms.

“Yeah it’s good to get checked, I mean if my risk is high I need to know if I actually do have it because I don’t have the symptoms so I wouldn’t know if I didn’t get checked.” (Participant 10, female, high risk, GP attender)

The above quote also suggests that the patient had trust and confidence in the screening tests and the high risk result it had given, and acknowledged the importance of knowing about the presence of such a condition.

Altruistic reasons were also given as the reason for attending for a diagnostic test. Some patients were motivated to seek a diagnostic test for the sake of their family.

“I needed to know really. I mean, I have to care for my husband at home twenty-four hours a day so I can’t afford to be ill else I wouldn’t be able to look after him any longer.” (Participant 8, female, high risk, GP attender)

“If I was diabetic, it would affect my children wouldn’t it. I need to know if I have something that would impact on them or increase their risk in the future.” (Participant 7, female, high risk, GP attender)

A popular reason for attending was because patients knew others who have or had diabetes so they understood the seriousness of the condition. Having known friends or relatives with diabetes led to a strong desire to prevent a similar fate for themselves.

“My friend is diabetic; she suffers awfully because of it.” (Participant 9, female, high risk, GP attender)

“My father had diabetes when he was alive, so I know what it can do to you. He lost his legs.” Participant 11, male, high risk, GP attender)

Finally, several patients explained that the reason for their attendance at the GP for follow-up was because they perceived their risk of diabetes to be high and they felt more susceptible to diabetes. This knowledge of their personal risk lead them to follow the advice they had been given. They had credibility and trust in the information they had been given in order to act on it.

“I think I went because I felt my risk was probably high after seeing you and doing the tests.” (Participant 12, male, high risk, GP attender)

“Yeah I went because you said my risk was high on both tests and you recommended I go and have another blood test so I just made an appointment as soon as I could. It’s a good job I did isn’t it.” (Participant 9, female, high risk, GP attender)

- *‘Why I did not go to my GP’*

Those patients who did not follow the advice to attend for GP follow-up reported several reasons for not doing so. One patient put it down to having low perceived risk and therefore did not feel the need to seek further investigation, despite the fact that the screening questionnaire identified a high level of risk.

“I know myself that my risk is low, so no I’m not at risk of it.” (Participant 16, male, high risk, GP non-attender)

There was evidence of denial and avoidance in some patients’ explanations for not going for GP follow-up. They downplayed the personalised risk information they had been given due to a lack of symptoms and feeling well in themselves.

“No I feel fine, like I don’t think I’ve got any of the symptoms so I doubt I’ve got it, I think I’m at low risk of it.” (Participant 14, female, high risk, GP non-attender)

“I don’t have it, I know I don’t because I feel fine and I’m fit and healthy. You wouldn’t if there was something up would you?” (Participant 18, male, high risk, GP non-attender)

Another reason for non-attendance was because there was no diabetes in the family.

“No one in the family is diabetic, so I doubt I’d get it.” (Participant 15, female, high risk, GP non-attender)

“I didn’t think there was much point in going, I mean there isn’t a history in the family of it so no I didn’t think I needed to.” (Participant 13, female, high risk, GP non-attender)

There were also reasons for non-attendance that seemed to be external to the individual. Several external barriers were given by non-attenders as reasons for not seeing their GP for follow-up. One of these barriers was a lack of time to see the GP due to work commitments.

“I work Monday to Friday eight till six. I can’t spare the time off unless I’m really ill.” (Participant 18, male, high risk, GP non-attender)

Additionally, there was a general dissatisfaction in some patients with their GP practice and appointment system.

“You want to try getting an appointment at my doctors’ surgery, it’s ridiculous! You can never get an appointment, even when you’re on deaths door.” (Participant 17, male, high risk, GP non-attender)

Finally, whilst being rather belief-based, one patient described that having to make the follow-up appointment themselves made it seem unimportant. There was a lack of seriousness and importance placed on the responsibility of seeking a follow-up diagnostic test if the GP wasn’t going to get in contact with them.

“Because you said to make the appointment myself, it just made it seem like it wasn’t that important if the GP wasn’t gonna follow it up and contact me” (Participant 15, female, high risk, GP non-attender)

Part two: What are dentists' views of screening for diabetes in dental settings?

Thematic analysis revealed two themes that reflected diabetes and its association to dentists as healthcare professionals: *Diabetes as a major health concern; Dentists as responsible healthcare professionals*. In addition, two themes were identified which reflected an evaluation of the screening programme conducted: *Ideal screening method to be easy, quick and can be administered by anyone; Limitations of such a screening programme*.

1. *Diabetes is important in the dental setting.*

Dental practitioners acknowledged that diabetes is a major health concern by reflecting on the knowledge that diabetes is a condition that is increasing in prevalence.

“The number of people developing it is definitely increasing. It’s becoming so common, it’s worrying” (Dentist 2, Staffordshire)

This can be seen again in the comment below too.

“We’re seeing more and more people marking it on their medical history forms.” (Dentist 3, Staffordshire)

Dentists also commented on their awareness of how diabetes affects other aspects of a person’s health. This demonstrated that dentists seemed to have a good working knowledge of how diabetes affects a person’s oral health. “

We know; It’s well documented you know, that diabetes affects other aspects of a person’s health, and we know it can impact upon the oral health of a person in several ways.” (Dentist 6, London)

It was also mentioned by dental practitioners that diabetes was a condition that was specifically documented in dental records and important to know. Dentists from the practice in Staffordshire described how the condition features on the medical history form that

patients complete or update before their appointment. Likewise, Dentists from the practice in London stated that there was a specific function on their computer software that allowed them to note a patient's diagnosis of diabetes.

“That’s why we ask about a history of diabetes on our medical history form that all patients have to complete; it’s major, it’s essential to know isn’t it” (Dentist 1, Staffordshire)

It was evident that knowing a patients' diagnosis of diabetes was important in the dental setting for potential treatment.

“Our patient medical history form requires patients to explicitly state if they have diabetes or not” (Dentist 4, Staffordshire)

Dentists from the practice in Catford stated that there was a specific function on their computer software that allowed them to note a patient's diagnosis of diabetes. Dentists seemed to demonstrate that diabetes is a condition that is well documented in a patient's dental notes so that they are aware of its existence and importance to a patient's overall health.

2. Dentists as responsible Healthcare Professionals

It was common for the dentists to acknowledge responsibility and that there is a place for them to intervene and be involved with diabetes screening or management of the condition.

“When it’s linked to what we know and what we do, of course we should be involved in detection and management.” (Dentist 5, London)

“We have a responsibility, a duty of care to our patients to ensure their health is the best it can be. I know I am responsible for my patient’s oral health but if I can help in any other aspects of their health when I see them, then yeah, I’ll feel it’s my responsibility to inform.” (Dentist 1, Staffordshire)

“I told a patient the other day that they should probably see their GP to get tested, if they’re showing signs of diabetes risk then I’m definitely responsible to recommend screening or follow-up.” (Dentist 1, Staffordshire)

Dentists also talked about the significance of having a good rapport with patients and how this would help patients to understand the importance of the risk of diabetes that was being conveyed to them.

“When you get on with patients, they trust you, they accept what you tell them whether that be to use a certain product or whether they risk developing diabetes; they’ll listen and hopefully do something about it.” (Dentist 2, Staffordshire)

The dentists expressed a belief that a good rapport would lead to patients accepting advice given by them and follow up any recommendation given; in this case, to follow up screening tests with diagnostic tests from their GP. The following quotes below are an example of this.

“I’d like to think if I told one of my patients they might be at an increased risk of diabetes, they’d see I was being responsible for their overall health as well as their oral health and go see their doctor.” (Dentist 3, Staffordshire)

3. Ideal screening method to be easy, quick but thorough, and can be administered by anyone

Dentists described their experience and views on the screening method that was conducted at their practices. They described the screening programme as ideal in that it was quick and easy and that it needed to be able to be administered by anyone who needed to do so.

“I was really impressed with the screening protocol that was done here. It was quick and easy, and the patients seemed to approve.” (Dentist 5, London)

Overall, the dentists had positive comments about the screening programme conducted at their practice. They liked the idea of the initial risk assessment questionnaire because of its ease and non-invasive nature.

“Yeah the questionnaire is great; it’s easy to do isn’t it for patients, like it’s not invasive is it so it’s good...most people can manage that.” (Dentist 4, Staffordshire)

They felt that the majority of patients would be happy to complete a questionnaire of this nature.

“The questionnaire...yes anyone can get the patient to fill it out; that’s the main advantage I think.” (Dentist 6, London)

Dentists also commented on the use of having two screening tests and that it was a good idea as it gave their patients the feeling of more options.

“Two different screening methods looks more thorough; it shows we are taking it seriously.” (Dentist 3, Staffordshire)

“Yeah like I think it’s good that there’s two tests, you don’t have to do both if you don’t want. Patients will like that I think.” (Dentist 1, Staffordshire)

“A questionnaire followed by a finger prick blood test I think is a good combination you know.” (Dentist 6, London)

Although the use of two tests was favoured by dentists, some believed that the finger prick tests would be seen to have more credibility or importance by patients.

“The questionnaire is good for speed and a quick assessment of risk, but I think patients see the blood test as more reliable, like that’s the result they’d pay attention to most, it’s like its more official; like that’s what their GP would do you know.” (Dentist 4, Staffordshire)

Several of the dentists described how they had received positive feedback from their patients about their experience of the screening programme. It was conveyed as being patient-friendly and overall providing a good experience to patients.

“We’ve had some great feedback from patients...like how it’s quick and easy to complete and that.” (Dentist 1, Staffordshire)

“I had patients say how easy it was to do, and that it was a good idea” (Dentist 5, London)

“They seem to really like the idea” (Dentist 2, Staffordshire)

Some of the dentists talked about the idea that the screening programme was a way of working together with a patients GP by working together with a patients GP on something that affects the work of both professionals and that there is some level of shared responsibility.

“Referring at risk patients to their GP for diagnostic testing is a good collaborative approach” (Dentist 6, London)

“It’s kind of reassuring that we can let GPs know of any patients we are concerned about to follow up. We can just screen for risk, then let the GP know and so they can check and diagnose. We can work together.” (Dentist 2, Staffordshire)

4. Limitations of such a screening programme

Although dentists generally talked about the screening programme positively, they did acknowledge several limitations that would need to be addressed.

Funding and cost of running the screening programme was a limitation that was mentioned by all dentists interviewed. Dentists were concerned about who would cover the cost of equipment and materials used and the costs of administration for conducting the screening programme.

“It’s all money isn’t it; it all costs.” (Dentist 4, Staffordshire)

“The thing is, who’ll cover the cost for the screening to be done if this were to be rolled out?” (Dentist 6, London)

“The problem is who pays for it; we would need some kind of funding from somewhere” (Dentist 1, Staffordshire)

Other practicalities such as a specific location in the dental setting for screening to take place was an issue raised with the dentists. If it was someone other than the dentist doing the screening, then the dental surgery itself is not necessarily practical. Privacy would also be needed too, therefore a private consultation room would be more ideal.

“Do we have a special area dedicated for screening to be done, in surgery, in an office; where; it’s those practicalities that need addressing too” (Dentist 5, London)

Another limitation that was discussed was the issue of time.

“Time is a big issue; we are a busy practice...appointment length for NHS patient appointments are short as it is.” (Dentist 6, London)

“It’s all extra time isn’t it.” (Dentist 1, Staffordshire)

They acknowledged the fact that patients needed to arrive early in time to participate before their appointment, and the importance of keeping to time so not to interfere with time set aside for the actual dental appointment where in the case of NHS patient appointments, the appointment length is already short and time is precious.

“We asked people to arrive early specially to take part didn’t we, but we couldn’t realistically do that, or could we? I’m not sure.” (Dentist 3, Staffordshire)

Finally, the idea of lack of man-power to administer the programme was addressed by dentists. There was concern over who would dedicate the time to carry out the screening. They questioned who’s job role it would come under, and also whether a dedicated member of staff would be needed to take on the responsibility of the work needed to go into running the screening programme successfully.

“Right now, we don’t have the man-power to properly carry this out currently.... not someone dedicated to do this properly.....not with all the administration that goes with it.” (Dentist 6, London)

The dentists did not want any of the responsibility for conducting the screening programme themselves or the workload that would be involved. They saw it as a job responsibility that another member of the team would need to take on.

“The downside I guess is who would be in charge of doing it....in who’s job description?” (Dentist 1, Staffordshire)

Discussion

The aim of this study was to explore dentists and patient’s views and experiences of the feasibility and acceptability of screening for diabetes in dental settings. To date, research in the area has been limited; largely relying on brief self-administered questionnaires (for example, Greenberg et al. 2015) or lacking experience of being involved in a screening programme itself (for example, Creanor et al. 2014). Therefore, this study represents a unique contribution to the understanding of dentist and dental patients’ actual experiences of screening for diabetes in the dental setting, and further, explores why dental patients did or did not follow up screening test results with diagnostic tests at their GP surgery.

The qualitative analysis revealed that knowledge of diabetes seemed to be high in the dentists interviewed and that they were aware of the seriousness of diabetes to their patients, therefore highlighting the importance of the condition featuring in the education of dentists. Dentists were aware of the increasing rates of diabetes and its relationship to oral health. Their knowledge and understanding therefore seems to be the reason behind why their practice involves noting the presence of diabetes when collecting a patient’s medical history information.

In contrast, whilst all of the patients said that they had heard of diabetes, correct knowledge of what the condition was somewhat poor, although there tended to be some agreement over the seriousness of the condition. Some of those interviewed were aware of the causal factors and treatments for diabetes, however, overall this finding is in line with previous research

suggesting that the general populations' knowledge of diabetes and its risk factors and complications is low (Deepa et al., 2014; Diabetes UK, 2000).

The dentists demonstrated in the interviews that they believed dental practitioners were responsible healthcare professionals who were accountable for all aspects of their patients' health where able and not just for their oral health. They also believed that having a good rapport with their patients would assist in being a responsible healthcare professional and that it would make it easier to talk to their patients if they had a good relationship with them as they would be more likely to take any advice given to them on board. Establishing rapport is an important step in the communication between doctor and patient, resulting in a positive effect on patient satisfaction and overall clinical outcomes (Al Ali & Elzubair, 2016). Good doctor communication skills are important in all aspects of patient care, including the dental setting. Good rapport helps to achieve an accurate diagnosis, build trust with patients, and improve compliance to treatment, overall patient satisfaction, and therapeutic outcome (Beck, Daughtridge, & Sloane, 2002). Dentists tend to focus on the diagnosis and treatment of oral diseases and tend to overlook their patient's other health problems, which are regarded the responsibility of medical practitioners. Likewise, doctors too tend not to deal with the oral health problems of their patients (Lo, 2014). Dentists in the current study believed that by screening for diabetes, they were working together with their patients GP, and that there was a shared level of responsibility. Oral health and systemic health are closely related (Lalla et al., 2011). These health problems can only be satisfactorily managed by treating both the oral disease/problem and the systemic disease at the same time through collaboration between dental and medical practitioners (Lo, 2014).

With regard to dental patients, whilst some did not see the worth of diabetes screening, the majority of those interviewed reported that screening for the condition was worthwhile, acknowledging that detection of diabetes would lead to better health outcomes. Again, this adds to previous research which found that in general, dental patients support the concept of diabetes screening in a dental setting (Creanor, 2014; Rosedale & Strauss, 2012). Here, some patients described the benefit of screening to be a win-win situation in that the outcome of knowledge of one's risk could only be seen as a positive outcome, despite the result.

The screening programme conducted in this research study was overall acceptable to dental patients with the majority of those asked recalling only positive experiences. The finding here adds to the previous research by indicating that patients found diabetes risk screening showed

the dentist was taking an interest in their overall health, therefore increasing satisfaction with the overall experience. Research suggests that patients have more confidence in dentists who have the ability to communicate care and compassion (Epstein 2003). Patients tended to believe it was a good idea to be screened and therefore acted on the advice to do so, therefore demonstrating the importance of satisfaction on adherence. Dentists have an ethical obligation and a duty of care to protect the well-being of their patients. A screening procedure to detect a serious, underlying, undiagnosed systemic condition, and that does not cause any harm to the patient, is in the patient's best interests (Sultan et al., 2014). This was apparent in the discussion of the acceptability of the screening programme by dental patients.

Traditionally, research has shown that the more invasive a screening test is, the more accurate it is perceived to be. An example of this was seen when compared with colonoscopy, an invasive colorectal cancer screening test, stool-based DNA testing, a far less invasive screening tool, received more favourable ratings on preparation and test-related features such as sample collection, perceived embarrassment and anxiety except for perceived accuracy, where the more invasive test, colonoscopy, was rated higher than the non-invasive test (Schroy & Heeren, 2005). In the current study, it seems that some patients agreed with this notion as some negative views that were expressed, were concerned with the idea of having to complete the questionnaire if a second screening test was still needed. It seems that these patients thought it was better to just do what was perceived as the more accurate test, which in this case was the invasive finger prick blood test.

In contrast, dentists liked the idea of an easy to administer questionnaire and having two tests for patient choice as opposed to just one, but with that came the need for reliable measures to be used and so dentists too felt that the finger prick blood test would be seen as more reliable and believable. Dental practitioners also agreed that the best screening method would be one that is quick and easy to administer, and one that anyone in the practice could administer. In this study the procedure was conducted by the researcher. Dentists appeared to like the idea of having someone else being able to carry out the screening measures on their patients rather than them having to do it themselves. They reported that patients had responded positively to the screening tests in discussions with them and so they placed an importance on the need for patient-friendly screening tests. Previous research has suggested that, whilst uptake may be influenced by the method used for screening, with less invasive methods associated with a higher uptake (van den Donk et al., 2011), greater perceived accuracy is placed on more invasive measures used (Schroy & Heeren, 2005). Finally, in evaluating the screening

method used, dentists seemed to feel a level of reassurance in referring their at-risk patients to the GP for further diagnostic testing. It was a way of helping patients identify any risk of diabetes without having to be responsible for, and involved in diagnosing the condition.

Dentists also discussed the limitations of the screening programme used. Whilst the programme was readily accepted by the dental practitioners, they were concerned about several issues: time taken to screen patients, the cost of offering such a service to their patients and having enough staff to carry out the duties involved in conducting such a service. It is well known that appointment times for NHS patients are short, and that dentists are pushed to carry out their work in such a short space of time allocated for appointments (Newton & Gibbons, 1996). Dentists were also concerned about having to find funds for such a service and that their NHS budget was already tight. Finally, whilst they liked the idea of a screening method that could be administered by any member of staff, they were concerned about having a member of staff available to carry out the screening. Extra duties might mean having to cut other responsibilities of some staff, or it may involve having to increase staff numbers in order for someone to be able to be fully responsible for the screening programme and the administrative duties that come with it.

Individuals can react with concern, anxiety and even depression when informed that they have an elevated risk of developing a disease (Collins, Wright, & Marteau, 2011). This distress can potentially interfere with the processing of the screening information such as risk results and hence the ability to be reassured or to make informed choices regarding future screening, follow-up or treatment. There was a mix of emotional reactions report in the results of this study. Positive emotions such as reassurance and relief were reported however, fear and worry were some of the negative emotional reactions to screening that were reported also. Interestingly, the dentists did not mention the possibility of negative reactions to the screening. It is not known whether the negative emotional reactions were short lived or not, however, several reviews in the area of psychological effects of screening suggest that any report of distress are not sustained long term (Collins et al., 2011), and of more significance, screening for type 2 diabetes has limited psychological impact on patients (Eborall et al. 2007). However, if dental practitioners are not consciously aware of any possible negative reactions to screening and its outcomes, it could mean that patients would not value their dentist and any rapport that has been built could be lost. On the other hand, dental practitioners may hold the belief that they have an ethical obligation and a duty of care to

protect the well-being of their patients, and when it comes to a screening procedure to detect a serious, underlying, undiagnosed systemic condition such as diabetes, the benefit to a patient outweighs any potential negative reaction.

Patients reported that their perceived risk and susceptibility changed over the duration of the screening programme. This seemed to be coming from learning of one's risk and the knowledge of risk factors that was seen from the screening questionnaire. This finding may show some support that perceived risk and susceptibility are in some way linked and have an association with screening participation, in that by participating in screening, a patient becomes aware and starts to think about how a particular condition, in this case, diabetes; can affect their health.

When discussing how their perceived risk changed over the duration of the screening programme, some patients recalled their risk information. Research has demonstrated that memory for medical information is a prerequisite for good adherence to recommended treatment (Kessels, 2003); in this case, seeing their GP for diagnostic follow-up. According to Ley's model of effective communication in medical practice (Ley, 1988), a significant proportion of the variance in compliance to medical advice can be accounted for by comprehension and memory, but research suggests that medical information tends to be forgotten immediately (Kessels, 2003). However, in this study, there was evidence of accurate recall of risk information by some patients. In the case where one patient inaccurately recalled the information given, the patient had misunderstood the risk information, downplaying it which lead to not adhering to the recommended advice to seek a diagnostic test from their GP.

There were several reasons given for attending or not attending the GP follow-up from those interviewed where it was recommended they do so. The fear of life threatening underlying disease has been reported to be a reason to seek help or advice (Wareing, 2005).

Reasons given in this study for attendance included the need for reassurance, the importance of early detection, altruism, high perceived risk, knowing others with diabetes, and simply following the recommendation to do so. Eborall et al. (2007) reported similar findings in that diabetes screening participants talked about diabetes screening being a good thing as it enabled the disease to be detected at an early stage. Altruism has often been a reason given for participating in cancer trials (Jenkins et al., 2013), however, altruistic reasons have also been given for lung cancer screening participation (Patel et al., 2012). In this qualitative study

looking at attitudes to participation in a lung cancer screening trial, the authors found that altruism was expressed by participants as the desire to help other people by taking part in the research and also as helping relatives by reassuring them that they did not have lung cancer. The finding that some patients reported attending the GP for diagnostic follow-up because they perceived their risk to be high, or because they were simply following the advice to do so suggests that these patients had some level of belief and credibility in the risk information they had been given. This finding is in contrast to a suggestion made by Eborall et al. (2007) that there may have been a lack of accepted professional understanding as the authors reported that participants with either some level of impaired fasting glucose or impaired glucose intolerance or those who tested negative for diabetes tended to downplay their risk, had no intention to change their lifestyle and lacked awareness of a diagnosis.

For publicly funded healthcare systems such as the NHS in the UK, when assuming adequate healthcare services exist to meet patient demand, access to these services is primarily dependent on patients' decisions (Shaw, Brittain, Tansey, & Williams, 2008). In this study, reasons for non-attendance for GP diagnostic follow-up in those patients who were recommended to do so included low perceived risk and severity, denial, and the belief that a lack of family history of diabetes was a protective factor. The latter supports the notion of unrealistic optimism; a cognitive bias that causes a person to believe that they are less at risk of experiencing a negative event compared to others. It has been shown that highlighting previously unknown risk factors for diseases is ineffective at altering peoples' optimistic perception of their medical vulnerability (Sharot, 2011). Underestimating risk is also thought to potentially reduce precautionary behaviour such as attending medical screenings (Sharot, 2011). This could therefore explain why those patients who believed that a lack of family history of diabetes was a protective factor did not attend for diagnostic follow up at the GP surgery.

In the wider literature, reasons given for non-help-seeking are often that symptoms are too mild, or not felt to be serious enough (Scott & Walter, 2010; Teunissen & Lagro-Janssen, 2004). This reason was somewhat reflected in the findings of this study in that severity of the disease was not enough to make the high risk patients attend the GP as recommended. A lack of symptoms was also reported as a reason for non-attendance in this study too. Unfortunately, as diabetes often occurs without the known presence of symptoms, this will be a barrier that will be hard to overcome unless addressed directly. Additionally, a lack of

awareness of both symptoms and treatment has been identified as barriers to help-seeking (Horrocks, Somerset, Stoddart, & Peters, 2004; Moser et al., 2006; Smith, Pope, & Botha, 2005; Teunissen & Lagro-Janssen, 2004). Therefore, often if symptoms do occur in those with undiagnosed diabetes, they are not easily recognised by the patient as a symptom, therefore there is a need for greater education and awareness of diabetes, its seriousness and its symptoms.

Previous negative experiences with health care providers (Rickwood, Deane, Wilson, & Ciarrochi, 2005; Teunissen & Lagro-Janssen, 2004) has also been reported in the literature as a barrier to help-seeking behaviour. In this study, participants described negative experiences with being able to make an appointment to see their GP. Whilst there may be other factors contributing to their reason for not seeing their GP for a diagnostic test as recommended, this is something that is almost out of the patients control as they are reliant on their being an adequate service provision to meet patient demand for appointments. Another common barrier to seeing a physician is a doctor's lack of responsiveness to patient concerns (Fitzpatrick, Powe, Cooper, Ives, & Robbins, 2004). Satisfaction with provider services may therefore impact perceptions of access to health care (Akinici & Sinay, 2003) and play a part in a patient deciding whether to seek help from their GP.

In a study carried out by Zhang and colleagues in the US, using a nationally representative sample, they found that lack of access to care significantly elevated the risk of going undiagnosed with diabetes. Limited access to health care, especially being uninsured and going without insurance for a long period was significantly associated with being a "missed patient" with diabetes (Zhang et al., 2008). In contrast, this is something that the UK population do not have to concern themselves with due to the provision of the NHS providing free healthcare for all. Therefore, this barrier should not apply to patients in the UK.

Strengths and weaknesses of the study

Qualitative methods are well suited to exploring attitudes and opinions. Data saturation was achieved and a range of participants who participated in the screening programme were interviewed. Whilst the validity of the findings was not checked through respondent validation by feeding findings back to a group of respondents, the interviews were digitally recorded and transcribed, thus eliminating potential bias through note-taking during interviews and steps were taken to ensure the credibility of the analysis.

Although questions were aimed at participants' experiences of diabetes screening and seeking further diagnostic tests for diabetes where necessary, it must be borne in mind that whilst the findings may apply beyond screening for the possible presence of diabetes, they may only be representative of screening behaviours in patients at risk of developing a particular condition. Findings must, therefore, be corroborated in other clinical and non-clinical groups. It could, however, be considered a strength that all participants had experienced screening and risk assessment and possibly diagnostic testing in a similar context (following initial diabetes screening at the dentist) to allow comparison between participants.

Age may also affect attitudes to health care and this study only sampled participants aged over 45 years due to the inclusion criteria set in the previous quantitative study from which participants were sampled. The findings, therefore, would need to be verified in a younger age group.

Reflective Commentary

The significance of reflexivity in qualitative research is well known. It is important to know how my position might have shaped the research process and outcome and acknowledge an important dimension of the research process and enhance the transparency of the research.

My own experiences of diabetes are what gave me interest in pursuing this study. My own mother has had diabetes for the whole of my life and growing up with a parent living with the condition has allowed me to see the negative effects it has on a person, long term. It has made me aware of how serious diabetes can be, and its complications. As a trainee health psychologist, I understand the importance of screening for disease. Therefore, knowing the seriousness of diabetes and the importance of early detection, I myself would pursue any screening available and would follow advice following risk assessment. Having this personal experience of diabetes did make me feel disheartened if a participant downplayed the seriousness of the condition or dismissed the risk information or advice to seek further diagnostic tests. On the other hand, I felt really pleased when participants discussed how they understood their risk of diabetes and followed up the advice to seek further diagnostic testing. I think this positivity came across in my interviews when speaking to those who followed up my advice.

My personal assumptions before conducting this study were that I would be met with participants not wanting to be interviewed. However, the majority of patients approached

were happy to be interviewed and this made the interview process pleasant and interesting. I felt at ease interviewing dental practitioners as I had been working alongside them for some time and had built a great rapport with all staff, and so they felt relaxed; this made me feel that what they were telling me actually was what they thought, rather than what they thought I may have wanted to hear. Whilst my rapport with them made the interviews seem informal, I was able to gather their thoughts and experiences on the screening conducted and their opinions and suggestions for its success in the future

As the researcher for the project, I was the one to take participants through the process of the study from information and consent, to diabetes screening and through to follow-up interview. Being a part of the journey of the participants through the study meant that participants had got to know me at the dental practice if they were returning for further treatment with the dentist and when speaking with them on the telephone to record their follow-up outcome or interview them. I believe this enabled me to build rapport and allowed participants to talk to me as more of a member of the dental practice team rather than a researcher external to their dental practice. I think this made them feel a bit more comfortable talking to me about what they actually thought and had experienced as opposed to wanting to please the researcher by saying what they thought the researcher wanted to hear, although this may have been the case.

After transcribing the data and when analysing and interpreting the data, I realised that some people really did not seem to have been affected in the way I would have hoped by the study; in that they still did not really see much point to diabetes screening and were not at all bothered by their risk results, whether they were high or low. By having these opinions and experiences though, it helped me realise that not everyone thinks about diabetes and its effects on a person like I do, and that helped me to not focus more so on the positives of the screening procedure that other talked about just because I shared the same views. It was important to reflect on these responses in the results as well as the ‘success stories’.

Conclusion

Many dental patients and dental practitioners believe that the dental visit is an opportune site for diabetes screening. By exploring both dental patient and practitioner experience, this particular screening diabetes screening method has been shown to be well tolerated, convenient and largely acceptable to patients. Several reasons for attendance and non-

attendance at the GP for diagnostic follow-up were identified by patients and practical limitations were noted by dental practitioners who experienced the screening method within their practice. This has implications for the uptake of screening within dental practice and will need to be addressed when taking this forward.

Chapter 8

Discussion

Summary of Findings

The overall aim of the research outlined in this thesis was to investigate the impact of using a self-report screening measure and HbA1c information as preliminary screening tools for possible diabetes in general dental practice, on patients' health behaviours. The primary outcome of the study was uptake of further diabetes diagnostic testing by the patients GP. A secondary outcome of the study was the ability of psychological variables to predict and explain uptake of further diagnostic testing following the receipt of a positive risk result either the FINDRISC along or with the addition of a positive risk result on the finger prick HbA1c blood test. Therefore, in order to address these outcomes, several research questions were set to be answered through conducting the studies in this thesis.

After an introduction to the topic of screening for diabetes in dental settings, chapter 3 addressed the first research question-

What is the most effective way to communicate individualised risk information to maximise either actual screening uptake or psychological predictors of screening uptake?

The question was answered through conducting a systematic literature review which found that individualised risk communication is more effective than generalised risk information or no risk information at increasing screening uptake or resulting in better psychological outcomes. Whilst presenting individualised risk information in written format and expressing the risk as an individualised score or category may be more effective at increasing screening uptake, the results suggested that more complex interventions, with more intervention components such as counselling or education, are no more effective than more simple interventions. These findings were then used to create the risk communication intervention which was designed to try to answer the subsequent questions.

Chapter 5 addressed further research questions. The first question tackled in this chapter was-

What proportion of dental patients accept an offer to be screened for type 2 diabetes in a primary care dental setting?

The results of the first part of the quantitative study showed that N=3700 NHS and private patients had a dental appointment during the 118-day recruitment period. N=2109 patients were excluded as they were either under 45 years of age (n=1888), did not speak fluent English (n=59), or already had diabetes/ pre-diabetes (n=162). A further 556 potential participants were not asked to take part as they either did not attend their appointment (n=121) or practically could not be tested by the single researcher (n=435).

Of the remaining 1035 patients, 520 (50.2%) consented to participate and completed the FINDRISC screening questionnaire. Five hundred and fifteen patients refused to participate in the study. The main reasons for refusal were, a recent blood glucose test, a recent health check-up such as the Well Man's Check arranged through the GP, dental pain and fear, and lack of interest in the research.

Following this, the next research question addressed was-

What is the risk of type 2 diabetes in primary care dental patients as assessed through self-report and physiological measures?

Two hundred and sixty-two participants scored below the cut off score of 10 on the FINDRISC questionnaire, and therefore were not offered any further screening. N=258 patients were found to be at risk of developing diabetes based on the current recommended FINDRISC cut off score of 10, and so were offered the further screening test, and advised to visit their GP for formal diagnostic testing. The majority of participants (n=247, 47.5% of those who took part) fell into the slightly elevated risk category, whilst N=101 (19.42% of those who took part) fell in the low risk category and N=172 (33%) were seen as having a moderate, high or very high risk of developing diabetes. Of the N=258 found to be at risk of developing diabetes on the FINDRISC, the majority (N=242, 93.8%) accepted and received the further screening HbA1c test. On this A1c test, 10 participants (4.13% of those who took the test) had a result of $\geq 6.5\%$, 108 participants (44.6% of those who took the test) had a result of between 5.7% and 6.4%, whilst 124 participants (51.24% of those who took the test) had a result of less than 5.7%.

Finally, the chapter addressed another research question-

What is the effect of personalised diabetes risk communication on subsequent health behaviours?

Of the N=259 participants who were advised to visit their GP for formal diabetes testing, N=155 (60%) contacted their doctor regarding an appointment for further testing.

There was a significant association between the number of 'at risk' screening results a person received and whether or not a patient would follow recommendation and contact their GP.

Furthermore, the number of positive risk scores significantly influenced GP contact; patients were more likely to contact their GP if they had received two positive risk scores. The odds ratio of patients contacting the GP was 3.38 times higher if they were referred with two positive risk results (both a positive FINDRISC and positive HbA1c risk result) as opposed to just one (a positive FINDRISC but negative HbA1c).

Chapter 6 then addressed two research questions. Firstly-

What is the psychological profile of patients at risk of diabetes?

Using the CES-D as a tool for detecting mild clinical depression, the mean score on the CES-D in those found to be at risk of diabetes on the screening measures was below the cut-off of 16, suggesting that, in this sample, those who were found to be at risk of developing diabetes, overall, did not have a score above the cut-off value for clinical depression. The participants found to be at risk of diabetes showed high levels of the belief of diabetes severity, and intention to have a diagnostic test but those participants who contacted their GP following screening felt significantly more vulnerable towards developing diabetes and significantly more fearful of the condition than those who did not contact their GP as advised to do so following screening.

The chapter then analysed the following question-

To what extent do psychological variables predict post-screening further testing or health behaviours?

The results of a binary logistic regression suggested that a high risk dental patient's fear of diabetes score and vulnerability to diabetes score were able to significantly predict whether a patient contacted their GP. This means that the more vulnerable people felt about the chance of developing diabetes in the future and the more fearful they were of the disease, the higher the chance they would make contact with the GP to arrange diagnostic testing.

A final research question was addressed in chapter 7, whereby, qualitative data was collected to try to answer-

What are patients' and dentists' views on the practicalities of screening for diabetes in dental settings, and can this help to further explain post-screening further testing or health behaviours?

Interviews with both GPs and dental patients found that many dental patients and dental practitioners believe that the dental visit is an opportune site for diabetes screening. By exploring both dental patient and practitioner experience, this particular screening diabetes screening method has been shown to be well tolerated, convenient and largely acceptable to patients. Several reasons for attendance and non-attendance at the GP for diagnostic follow-up were identified by patients and practical limitations were noted by dental practitioners who experienced the screening method within their practice.

Results in relation to previous research

When comparing the findings from the current set of studies described here in this thesis to previous research, firstly, the systematic review results were in line with previously conducted systematic reviews on the subject which suggest that average and high risk participants do as well as each other in risk interventions whilst simple interventions are as effective as complex ones (Edwards et al., 2013). Equally, providing individualised risk about one rather than several diseases may be better for outcomes. The role of a limited capacity attention processor may explain this finding; where the risk of just one disease is presented, individuals are more likely to be able to focus and process the information in order to make a decision about attending for screening (Kahneman, 1973). The majority of successful studies presented IRC information in writing, or in combination with another format (e.g. such as verbally in person) so there seems to be a substantial amount of support of its effect on screening uptake. This may be because participants preferred to have the information to hand to review again, or to take in at their own pace. The systematic review also builds on the findings from Edwards et al. (2013) and compliments their latest review reporting that most risk communication work is on cancer, although a few other conditions have recently been examined (Edwards et al., 2013). Since their review, there have been some other clinical topic areas examined, such as prostate cancer and osteoporosis and mixed clinical topic conditions, where studies have examined risk of developing several diseases or conditions together.

As with the previous US and UK studies, the first part of the quantitative study described in this thesis found that many dental patients were happy to participate and receive one or more

diabetes screening tests offered to them. The results showed a successful uptake of dental patients for diabetes screening, with 50% of eligible patients consenting to participate. However, the refusal rate of N=515 was higher than the figure stated in Wright et al. (2014). Several reasons for this can be offered, such as, that potential participants are much more likely to take part in research that is concerned with an issue which is particularly relevant to the participants' lives, overall there is a decline in willingness to participate in scientific studies in Western countries, which may hold little immediate benefit to the participant (Galea & Tracy, 2007). Finally, participants may be wary of committing their involvement to research that is likely to take up a substantial amount of their time given how scientific research has become increasingly demanding over the last decade (Galea & Tracy, 2007).

Almost half of dental patients screened using the FINDRISC were found to be at risk of developing diabetes based on the current cut-offs. In line with previous work, the majority of participants fell into the slightly elevated risk category, with a personalised risk score of between 7 and 11 (Costa et al. 2013). Wright et al. (2014) found that 84% of dental patients screened had at least some increased level of risk of diabetes, based on the NICE guidance tool which included a risk questionnaire and BMI measurement. The sample used in the current study, based on the risk questionnaire alone showed a similar result; that N=419 (81%) of the 520 participants had some level of elevated risk of diabetes. When looking at the results the point of care HbA1c measure, N=118 (45% of those taking the test) had a score of $\geq 5.7\%$ suggesting a risk of pre-diabetes and diabetes. Compared to 30% found by Herman and colleagues (Herman et al. 2015) and 40% in the participant sample of Genco and colleagues (Genco et al. 2014), the current result is slightly higher, probably because only those with FINDRISC score over 10 were offered the HbA1c test. The majority of participants (94%) scoring 10 or higher on the FINDRISC were happy to have their HbA1c measured by the researcher. Therefore, these results further support the notion that dental patients are happy to be screened for diabetes using a combination of a simple questionnaire and a more invasive finger-prick blood test.

Crucially, a high proportion (60%) of those advised to visit their GP for further formal diabetes testing followed this advice and contacted their GP. This is a much more promising result than found previously. For instance, Wright et al (2014) reported that only 20% of patients identified as at risk of developing diabetes attended their GP. Genco et al (2014) reported that 35% attended their GP for follow up; though there was a significant difference

in follow-up rates between patients referred from a community health centre where over 78% attended their GP compared to only 21% from private dental offices.

A recent study looking at EPPM and HBM predictors involved in the prevalence of colorectal cancer screening among community dwelling Chinese older people (Leung et al., 2016) found that EPPM variables fear and fatalism were not significant in predicting colorectal cancer screening. However, the current study found that fear was able to predict whether a patient contacted their GP for a diagnostic test following diabetes screening. Another recent publication by Birmingham et al. (2015) examined the impact of a personalised, remote risk communication intervention on behavioural intention and colonoscopy uptake in relatives of colorectal cancer patients. The original additive model showed poor fit, but when an alternative model in which each theoretical construct contributes uniquely, the model showed good fit. Cancer susceptibility and colonoscopy self-efficacy perceptions predicted intention to screen, which was significantly associated with colonoscopy uptake; both of which were not able to significantly predict uptake of diagnostic testing in the current study. A further study which looked at the adoption of mammography screening in Iranian women and the effective EPPM factors on mammography session attendance found that self-efficacy could predict mammography behaviour in the sample (Vatannavaz & Taymoori, 2014). Again, this was another EPPM theoretical component which was not a significant predictor of GP contact in the current study. These findings casts uncertainty as to what else might be contributing to the decision for patients to contact their GP for a diagnostic test. It also suggests that the EPPM might not be a good model to use to predict GP contact following diabetes risk screening, as even when two of the model variables significantly predicted the outcome, their effects were small, and therefore only slightly relevant.

Finally, the qualitative study described in this thesis represents a unique contribution to the understanding of dentist and dental patients' actual real views and experiences of screening for diabetes in the dental setting, and further, explores why dental patients did or did not follow up screening test results with diagnostic tests at their GP surgery. Previous research has suggested that the general populations' knowledge of diabetes and its risk factors and complications is low; the findings here found similar results. The findings also add to previous research which found that in general, dental patients support the concept of diabetes screening in a dental setting (Creanor et al., 2014; Rosedale & Strauss, 2012). The screening programme conducted in this research study was overall acceptable to dental patients with the majority of those asked recalling only positive experiences. The finding here adds to the

previous research by indicating that patients found diabetes risk screening showed the dentist was taking an interest in their overall health, therefore increasing satisfaction with the overall experience.

Traditionally, research has shown that the more invasive a screening test is, the more accurate it is perceived to be. Schroy et al. (2005) demonstrated that when compared with colonoscopy, an invasive colorectal cancer screening test, stool-based DNA testing, a far less invasive screening tool, received more favourable ratings on preparation and test-related features such as sample collection, perceived embarrassment and anxiety except for perceived accuracy, where the more invasive test, colonoscopy, was rated higher than the non-invasive test. In this study, it seems some patients agreed with this notion as some negative views expressed were concerned with the idea of having to complete the questionnaire if a second screening test was still needed. It seems that they thought it was better to just do what was perceived as the more accurate test, which in this case was the invasive finger prick blood test.

Methodological Issues

Issues related to the study sample

The participants in the current research studies were all aged over 45 as it is a known risk factor that diabetes risk increases from this age. This age limit might mean that the findings cannot be generalised to those under the age of 45. This is not a limitation of the research though as in the context of diabetes risk screening, there is a limit to the worth of screening for type 2 diabetes in those under the age of 45, as it is known that diabetes risk increases after the age of 45. However, as a methodological issue, restricting the age limit for participation might make recruitment more restrictive, where in a dental setting, there is a wide age range of patients being seen. However, if research was conducted which screened a wider range of the population, aged younger than 45 for instance to look at other risk factors for diabetes other than age, then the findings from the current studies would need to be generalised with caution as every participant in the current set of studies had at least one risk factor; that being aged 45 or over (Harris et al., 1998).

The research was conducted at two dental practices in the UK; one in London and the other in Staffordshire. This means that the findings must be generalised with caution to other parts of the country where the socio-economic status, ethnicity, and other types of people who differ

in terms of diabetes risk, may differ. The locations of the dental practices where recruitment took place are geographically and socio-economically very different, meaning that risk factors throughout the population in both locations would be different. Future research would benefit from recruiting participants from other parts of the UK.

One rationale for conducting the diabetes screening programme in a dental setting is because research has suggested that a large proportion of the UK population see a dentist at least once a year and healthcare utilisation patterns indicate that individuals tend to seek routine and preventive oral health care more often than routine and preventive medical healthcare (Glick & Greenberg, 2005). However, in the quantitative study conducted for this thesis, the researchers asked those participants identified as at risk of developing diabetes, to visit their GP for a diagnostic test. Therefore, the previous research might suggest that the visit to their GP for preventative medical healthcare is less likely to take place.

Issues related to the intervention content

The FINDRISC risk questionnaire is a self-report measure of diabetes risk. Whilst the researcher checked patients' height and weight to calculate their BMI, other questions may not have been answered accurately, therefore not giving a true representation of their risk score.

HbA1c was only measured in those participants who scored highly enough on the FINDRISC questionnaire to qualify for the further screening test. Thus, those in our sample who did not score highly enough on the FINDRISC to qualify for the second screening test (though accurate or exaggerated self-reports); the HbA1c test, may well have had an elevated HbA1c score, therefore increasing the percentage of overall participants with a high risk HbA1c score of $\geq 5.7\%$.

Issues with the Quantitative study

The screening procedure involved a validated risk questionnaire completed by all consenting participants and a fingerprick blood test measuring an individual's HbA1c for those identified as at risk of developing diabetes from the questionnaire. One particular issue with this method was that it was not possible to compare FINDRISC scores and HbA1c blood test results because not everyone received the fingerprick blood test. This means that it was not

possible to see if there was a correlation between the two risk results and assess each of the screening tests' performance.

Another issue encountered through the recruitment of dental practices for access to dental patients was that General Dental Practitioners were not keen to participate when approached. Only two of 50 dental practices were recruited in the end from where data collected took place. However, those practitioners who did take part were pleased with the screening programme that was conducted and were positive about the study and how it worked. Therefore, it would be necessary to explore how to market such a screening process in dental practices in order to recruit more dental practices.

Issues with the Qualitative study

It is possible that the audio recording of the qualitative work did have an impact on participants. It has been noted that participants' awareness of the presence of recording devices is believed to have a detrimental effect on the 'authenticity' or 'naturalness' of the data collected (Speer & Hutchby, 2003). They describe the one-way mirror effect, which is based on the idea that there is a realm of social interaction that is natural which is disturbed or diluted by the presence of the researcher and more specifically, their recording device. Speer and Hutchby (2003) further explain that it is implied that 'natural' interactions may only be captured in research if the researcher is able to stand behind a one-way mirror unnoticed by the participants. Audio recording has also been found to make some participants anxious, and it has also been suggested that the use of a recording device may limit rapport and possibly "interfere with participant observation" (Judd, Smith, Kidder, & Kidder, 1991).. However, in the case of the qualitative study in the current research, interviews with dental patients were conducted over the telephone, therefore the presence of a recording device might have been lessened with the interviews not being conducted face to face.

Strengths of the Research

A major strength of the current research was the mixed methods approach. It was useful to capitalise on the benefits of both qualitative and quantitative methods. There is a lack of previous research carried out in the area of diabetes risk screening and follow-up behaviour in the UK, and so it was considered important to carry out thorough research to explore the impact of individualised diabetes risk information on participants' subsequent behaviour. By

using both methods, it was possible to draw fuller conclusions about the effectiveness of the individualised risk communication and screening tests on subsequent behaviour. From the quantitative work, it was possible to measure high risk participant's attitude to diabetes and screening and quantitative summarise contact made with their GP. From the qualitative work, it was possible to examine participants' thoughts and feelings about the screening methods used and the effect this had on their subsequent behaviour in terms of making contact with their GP.

Another strength of the research was the addition of GP confirmation to ascertain participant contact with their GP. When measuring the follow up outcome to see if those participants advised to see their GP for a diagnostic test actually did so, we contacted those participants and measured self-reported contact with their GP. However, we also wrote to all GP's and asked them to return a reply slip confirming the outcome to either support the self-reported response or provide the outcome in instances where participants were unable to be contacted. The response rate for GP confirmation letters was 78.76%. This was higher than expected to complement the patient reported outcomes, as it was expected that GP's would be too busy to respond. This response from GP's meant that outcome data was strengthened by their confirmation.

Implications for theory, research and practice

Theoretical Implications

The theory of risk homeostasis (Wilde, 1998) proposes that individuals adjust their behaviour based on their perceived level of risk of an outcome (risk perceptions) and the level of risk that they are willing to assume. The theory hypothesises that individuals who perceive that their risk of a negative outcome is low (for example, after receiving an intervention like diabetes screening) may participate in less safe behaviours such as visiting their GP for a diagnostic test, or eating more and exercising less. Therefore, by screening for diabetes and giving a person a low risk outcome, or telling a person that although their risk was high on one test, but low on another, they might decide that they do not need to visit their GP for a diagnostic test, or be so mindful of their diet and exercise regime.

Currently, the EPPM frequently features in health and risk communication literature applied to many health behaviours such as smoking (Thrasher et al., 2016), cancer screening (Leung et al., 2016) and kernicterus risk (Russell, Smith, Novales, Massi Lindsey, & Hanson, 2013).

The EPPM has not been applied to diabetes diagnostic testing before now, therefore the findings from the current set of studies provide a starting point. The current set of studies provided an important examination of how the EPPM framework may aid in interventions to motivate diabetes screening and diagnostic testing intentions and behaviour. The findings in chapter six do support some of the key theoretical tenets of the EPPM and can be used to guide the development and implementation of effective interventions to promote diabetes screening, though they should not be relied upon, as due to small effect sizes, they are only slightly relevant. Not all EPPM components were predictive of post-screening diagnostic testing in the current set of studies. The question arises as to whether we should just abandon the theory, or whether another theoretical model would be more successful at predicting diagnostic testing. Further research is needed to continue to test the EPPM, because it has been successfully used to predict behaviour outcome in other health screening settings. Future research could also look to modify the predictors to see if a better model of fit can be found. The EPPM's theoretical concepts are thoroughly developed, but the theory lacks consistency in operational definitions of some of its constructs (Popova, 2012). The usefulness of this theory to communication researchers lies in its ability to generate research and to potentially serve as a foundation for the general parallel process model of negative emotional appeals.

Practical Implications

Due to the lack of interest from General Dental Practitioners to have their practice participate in the study, there might be problems with recruiting practices in the future should this study be repeated or screening programme be rolled out as a service. Therefore, it is important to explore how to market such a screening programme so that practitioners want their practice to be involved.

The current research has demonstrated that it is possible to conduct a diabetes screening programme in a dental practice. However, in reality, there will always be issues with costs and funding.

If the aim is to ensure patients found to be at risk of diabetes through screening tests to have a diagnostic test, then perhaps, rather than relying on psychological predictors to guide us, there might be more practical things that can be done in the dental setting to ensure this

happens. For example, as healthcare practitioners, it might be possible for a dentist or nurse with phlebotomy training to take blood for the diagnostic test themselves rather than rely on patients having to go to their GP. This would mean that GPs are less heavily relied upon, and dentists are seen as having more input on systemic health as well as oral health. However, there might be an issue with cost, and who might fund this; an issue which was raised by interviewed dentists in the qualitative study in chapter 7. Further to this, dentists are well equipped to offer health advice and education relating to diabetes (Tavares et al., 2012), and could help to educate their patient on the risks of T2D, advice on making lifestyle changes in order to reduce their risk of diabetes, and the importance of diagnostic testing if needed. This would mean that GPs aren't having to expect fear of diabetes to encourage their patients to see their GP for a diagnostic test. Finally, it might be possible to make arrangements for a patient to receive a diagnostic test from their GP over the phone, or have a direct referral system in place with GP surgeries, where once informed, the GP surgery can make contact with the patient to offer an appointment for a diagnostic test, rather than the patient having to make the initial contact. This might help patients to feel that the issue is more of a priority if the GP surgery makes contact with them rather than the other way around; a comment that was made by patients when interviewed in the qualitative study in chapter 7.

Clinical Implications

Current evidence suggests that discussing health risks using simple risk scores or categories and providing this information in writing, may be successful in supporting people to consider undertaking health screening. There are of course cost implications to any intervention. What is promising is that the more complex interventions (which presumably, by their very nature, are more costly) do not appear to be any more effective than simpler interventions.

Unfortunately, the current studies were not able to say if the FINDRISC was correlated with HbA1c results, therefore we cannot say whether the questionnaire could replace the blood test in clinical settings to reduce cost and save time. However, the current set of studies showed that by being screened with two tests increased the likelihood of GP attendance for diagnostic testing.

Directions for future research

Before clinical recommendations can be made as to the potential for diabetes screening to be incorporated into routine dental examination, future research is needed to assess the economic cost of screening via the methods conducted in the current study, and also the issue of the time it takes to conduct, especially in busy NHS dental practices. Consideration should also be given to the inclusion of diabetes screening in private dental practice where patients pay for non-NHS treatment where such a screening programme could be charged for additionally.

Feasibility studies are appropriate when there is robust evidence to validate a larger study, and where the nature and structure of the study is known, but where important practical information is needed to make the potential study clearly fundable. Therefore, a study to assess the feasibility of screening for diabetes in the dental setting is needed to assess the economic cost and the time issues that have not yet been assessed. Bowen and colleagues discuss the several areas of focus that are addressed when conducting a feasibility study (Bowen et al., 2009). Whilst the current studies have focussed upon the acceptability of the screening intervention and the demand when looking at the number of dental patients accepting screening, other areas of focus such as adaptation, practicality and expansion were beyond the scope of this thesis, therefore further studies to assess the feasibility of the intervention are needed.

Current Outlook

A recent damning report by BBC Panorama suggested that Britain is in the grip of a health epidemic that is threatening to overwhelm the NHS. According to their broadcast on the issue, the number of people, especially children, diagnosed with type 2 diabetes is rising alarmingly fast, with one person being diagnosed in the UK every two minutes. Their report suggests around four million people in the UK have Type 2 diabetes. It's a major problem that is costing the NHS roughly £10.3billion a year - almost 10% of its overall budget; with that, the BBC propose that the NHS will not survive the costs of this diabetes epidemic. The UK National Screening Committee's policy is that general population screening for diabetes should not be offered. However, diabetes risk assessment is offered to people aged 40–74 years in England as part of the NHS Health Check.

The studies described in this thesis do suggest that screening for diabetes is accepted by dental patients in primary care dental settings. We now know that receiving two positive screening tests influences GP contact compared to receiving just one positive screening test. In addition to this, fear of diabetes and feeling vulnerable towards diabetes does increase the chances that dental patients will seek a diagnostic test following initial diabetes screening. Therefore, individualised diabetes risk should be communicated to dental patients to reduce the possible risk of developing diabetes through early detection behaviour.

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Appendix 1: Search strategies and published article – Systematic review

Medline Search Strategy

1. Models, Psychological/
2. social cognition*.mp.
3. social cognition model*.mp.
4. health belief model.mp.
5. HBM.mp.
6. theory of planned behavior?r.mp.
7. TPB.mp.
8. theory of reasoned action.mp.
9. TRA.mp.
10. perceived behavior?ral control.mp.
11. protection motivation theory.mp.
12. PMT.mp.
13. protection motivation.mp.
14. cues to action.mp.
15. (knowledge adj5 screen*).mp.
16. (knowledge adj5 risk*).mp.
17. (knowledge adj5 attend*).mp.
18. (attitude* adj5 intention*).mp.
19. (attitude* adj5 screen*).mp.
20. (attitude* adj5 attend*).mp.
21. Self Efficacy/
22. self efficacy.mp.
23. exp Disease Susceptibility/
24. (susceptibility adj5 screen*).mp.
25. (susceptibility adj5 disease*).mp.
26. ((susceptibility or severity) adj5 threat*).mp.
27. (threat adj3 cop*).mp.
28. ((adaptive or maladaptive) adj3 cop*).mp.

29. (barrier* adj5 health*).mp.
30. (barrier* adj5 benefit*).mp.
31. ((barrier* or benefit*) adj5 screen*).mp.
32. (intention* adj5 attend*).mp.
33. (intention* adj5 screen*).mp.
34. (behavio?r* adj3 intention*).mp.
35. subjective norm*.mp.
36. Motivation/
37. motivation*.mp.
38. exp Health Behavior/
39. health behavio?r*.mp

- 40.** 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39

- 41.** Mass Screening/
42. mass screen*.mp.
43. screen* or screening* or health screen*.mp.
44. (screen* adj5 (participat* or attend* or uptake)).mp.
45. Genetic Testing/
46. gene* test*.mp.
47. screen* test*.mp.
48. Mammography/
49. mammo*.mp.
50. Vaginal Smears/
51. vaginal smear*.mp.
52. cervical smear*.mp.
53. Occult Blood/
54. (fecal occult blood or occult blood).mp.
55. Prostate-Specific Antigen/
56. prostate-specific antigen.mp.
57. Colonoscopy/ or Sigmoidoscopy/
58. (Colonoscopy or Sigmoidoscopy).mp

59. exp early diagnosis/

60. 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59

61. exp risk/

62. risk*.mp.

63. ((tailor* or individual* or personal*) adj5 (message* or risk*)).mp.

64. ((patient* or consumer* or recipient*) adj5 (tailor* or personal* or individual*)).mp.

65. 61 or 62 or 63 or 64

66. Communication/

67. Health Communication/

68. Persuasive communication/

69. Counseling/

70. Genetic Counseling/

71. health education/

72. Patient Education as Topic/

73. Health Knowledge, Attitudes, Practice/

74. exp Decision Making/

75. Choice Behavior/

76. exp Attitude to Health/

77. Health promotion/

78. health promotion.mp.

79. exp "Patient Acceptance of Health Care"/

80. Informed Consent/

81. ((patient* or consumer*) adj3 (communicat* or counsel* or inform* or discuss* or decision* or decide* or participat*)).mp.

82. 66 or 67 or 68 or 69 or 70 or 71 or 72 or 73 or 74 or 75 or 76 or 77 or 78 or 79 or 80 or 81

83. 40 and 60 and 65 and 82

84. randomi?ed controlled trial.pt

85. controlled clinical trial.pt

86. randomi?ed.ab

87. placebo.ab

88. trial.ti

89. 84 or 85 or 86 or 87 or 88

90. 83 and 89

91. exp animals/ not humans.sh.

92. 90 not 91

93. Limit 92 to English language

EMBASE Search Strategy

1. psychological model/
2. social cognition/
3. social cognition*.mp.
4. social cognition model*.mp.
5. health belief model/
6. health belief model.mp.
7. HBM.mp.
8. theory of planned behavior/
9. theory of planned behavior?r.mp
10. TPB.mp.

11. theory of reasoned action/
12. theory of reasoned action.mp.
13. TRA.mp.
14. perceived behavioral control.mp.
15. protection motivation theory.mp.
16. protection motivation.mp.
17. PMT.mp.
18. cues to action.mp.
19. (knowledge adj5 screen*).mp.
20. (knowledge adj5 risk*).mp.
21. (knowledge adj5 attend*).mp.
22. (attitude* adj5 intention*).mp.
23. (attitude* adj5 screen*).mp.
24. (attitude* adj5 attend*).mp.
25. self concept/
26. self efficacy.mp.
27. cancer susceptibility/
28. genetic susceptibility/
29. (susceptibility adj5 screen*).mp.
30. (susceptibility adj5 disease*).mp.
31. ((susceptibility or severity) adj5 threat*).mp.
32. (threat adj3 cop*).mp.
33. ((adaptive or maladaptive) adj3 cop*).mp.
34. (barrier* adj5 health*).mp.
35. (barrier* adj5 benefit*).mp.
36. ((barrier* or benefit*) adj5 screen*).mp.
37. (intention* adj5 attend*).mp.
38. (intention* adj5 screen*).mp.
39. (behavior* adj3 intention*).mp.
40. subjective norm*.mp.
41. motivation/
42. motivation*.mp.
43. exp health behavior/
44. health behavior*.mp.

45. genetic screening/
46. mass screening/
47. screening/
48. cancer screening/
49. screening test/
50. mass screen*.mp.
51. screen* or screening* or health screen*.mp.
52. (screen* adj5 (participat* or attend* or uptake)).mp.
53. gene* test*.mp.
54. screen* test*.mp.
55. mammography/

56. mammo*.mp.
57. vagina smear/

58. vagina* smear*.mp.
59. cervical smear*.mp.
60. occult blood/

61. occult blood or fecal occult blood.mp.
62. prostate specific antigen/

63. prostate-specific antigen.mp.
64. Colonoscopy/ or Sigmoidoscopy/
65. (Colonoscopy or Sigmoidoscopy).mp
66. exp early diagnosis/

67. exp risk/
68. risk*.mp.
69. (tailor* or individual* or personal*) adj5 (message or risk).mp.
70. (patient* or consumer* or recipient*) adj5 (tailor* or personal* or individual*).mp.

71. interpersonal communication/

72. persuasive communication/ or

73. verbal communication/

74. medical information/

75. counseling/

76. genetic counseling/

77. patient education/

78. health education/

79. health promotion/

80. health promotion.mp.

81. exp Attitude to Health/

82. informed consent/

83. decision making/

84. ((patient* or consumer*) adj3 (communicat* or counsel* or inform* or discuss* or
decision* or decide* or participat*)).mp.

randomi?ed controlled trial.pt.

controlled clinical trial.pt.

randomi?ed.ab.

placebo.ab.

clinical trials as topic.sh.

randomly.ab.

trial.ti.

exp animals/ not humans.sh.

Limit to English language

Web of Science Search Strategy

social cognition*

social cognition model*

health belief model

HBM

theory of planned behavior?r.mp.

TPB.mp.

theory of reasoned action.mp.

TRA.mp.

perceived behavior?ral control.mp.

protection motivation theory.mp.

PMT.mp.

protection motivation.mp.

cues to action.mp.

(knowledge same screen*).mp.

(knowledge same risk*).mp.

(knowledge same attend*).mp.

(attitude* same intention*).mp.

(attitude* same screen*).mp.

(attitude* same attend*).mp.

self efficacy.mp.

Disease Susceptibility.mp.

susceptibility

(susceptibility same screen*).mp.

(susceptibility same disease*).mp.

susceptibility same threat*

severity same threat*

(threat* same cop*

adaptive same cop*

maladaptive same cop*

(barrier* same health*).mp.

(barrier* same benefit*).mp.

((barrier* same screen*

benefit* same screen*

intention* same attend*

intention* same screen*

behavior* same intention*

behaviour* same intention*

subjective norm*.mp.

motivation*.mp.

health behavior?r*.mp.

or/1-35

mass screen*

screen*

screening*

health screen*

screen* same participat*

screen* same attend*

screen* same uptake

gene* test*

screen* test*

mammo*

vagina* smear*

cervical smear*

fecal occult blood

occult blood

prostate-specific antigen

Colonoscopy

Sigmoidoscopy

early diagnosis

or/37-48

risk*.mp.

risk assess* .mp.

genetic risk.mp.

cancer risk.mp.

((tailor* or individual* or personal*) same (message or risk)).mp.

((patient* or consumer* or recipient*) same (tailor* or personal* or individual*)).mp.

or/50-55

Communication.mp.

Health Communication.mp.

Persuasive communication.mp.

Counsel*.mp.

Genetic Counsel*.mp.

health education.mp.

Patient Education.mp.

Decision Making.mp.

Attitude* to Health.mp.

health promotion.mp.

((patient* or consumer*) same (communicat* or counsel* or inform* or discuss* or decision* or decide* or participat*)).mp.

or/57-68

36 and 49 and 56 and 69

PubMed Search Strategy

social cognition*

social cognition model*

health belief model

HBM

theory of planned behavior OR theory of planned behaviour

TPB

theory of reasoned action

TRA

perceived behavioral control OR perceived behavioural control

protection motivation theory

PMT

protection motivation

cues to action

knowledge

attitude*

intention*

self efficacy

self-efficacy

Disease Susceptibility

Susceptibility

adaptive coping or adaptive coper*

maladaptive coping or maladaptive coper*

barrier*

benefit*

behavior* intention* or behaviour* intention*

subjective norm*

motivation*

health behavior* or health behaviour*

COMBINE above with OR

mass screen*

screen*

screening*

health screen*

screen* participation

screening attendance

screening uptake

gene* test*

screen* test*

mammo*

vagina* smear*

cervical smear*

fecal occult blood

occult blood

prostate-specific antigen

Colonoscopy

Sigmoidoscopy

early diagnosis

COMBINE above with OR

risk*

risk assess*

genetic risk

cancer risk

tailored message

individual* message

personal* message

individual* risk

personal* risk

COMBINE above with OR

Communication

Health Communication

Persuasive communication

Counsel*

Genetic Counsel*

health education

Patient Education

Decision Making

Attitude* to Health

health promotion

COMBINE ABOVE WITH OR

A systematic review of the effect of individualized risk communication strategies on screening uptake and its psychological predictors: the role of psychology theory

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Abstract

People might be more likely to attend for health screening if they are told their individual risk of an illness. The way this risk of ill-health is communicated might have an effect on screening uptake or its psychological proxies. It is possible that the format, presentation, and details of the information as well as the complexity of an intervention and use of psychological theory to inform the intervention may impact the effectiveness of individual risk communication. This systematic review collates, analyses and synthesizes the evidence for effectiveness of these aspects of individual risk communication. The synthesis indicated that written, individualized risk scores or categories are effective at supporting screening uptake and its psychological proxies. Complex, or theory-based interventions, surprisingly, are no more effective than simpler or atheoretical interventions.

Introduction

A significant proportion of mortality from the leading causes of death in the industrialized world is due to modifiable behavior patterns (Connor and Norman, 2005). The psychological predictors of such health behavior patterns (e.g. attendance for screening) have been researched extensively and several social cognition models

(SCMs) have been put forward e.g. Health Belief Model, Protection Motivation Theory (Connor and Norman, 2005). Psychological theory such as SCMs often focuses on predicting health behavior through the notion of threat or risk. For instance, people consider, amongst other psychological factors, their risk for a particular condition before choosing to engage in a health behavior. SCMs seeking to predict adherence to health behaviours suggest that people consider their risk for a particular condition, whether it is expressed as their perceived risk, perceived susceptibility, or their perceived severity for developing a disease, before engaging in any health behaviour. Therefore, targeting an individual's understanding of their own risk for a particular disease may lead to behavior change, such as screening uptake by enhancing behavior-change proxies such as intentions to undertake screening, knowledge and attitudes etc. Therefore, theory-driven research would suggest that risk is an important concept to examine, so that an individual's understanding of their own risk for a particular disease or condition can be targeted to inform the decision to undergo screening.

There is a diverse range of tests and screening programs that can be used to identify those who are *at risk* of developing various diseases or conditions. Many of these tests aim to differentiate between those who probably have a disease, and those who probably do not, or aim to highlight a risk of disease (Edwards *et al.*, 2006). Screening programs often provide information about population risks of developing a disease to inform decision-making regarding screening, or they aim to motivate people to attend for testing in order to maximize screening uptake (Edwards *et al.*, 2013). However, not all studies in the field use theoretical models to design their interventions, and not all screening programs offer individualized risk information. A popular way to target and improve screening uptake is to provide information that is personally relevant; often known as individualized risk. Recent systematic reviews have reported evidence of enhanced informed decision-making in those who received individualized risk information with, surprisingly, highly detailed risk communication, predicting *lower* screening uptake (Edwards *et al.*, 2006; 2013). Proxies of screening uptake were considered in the review, but the theoretical background of the reviewed studies was not investigated. Another systematic review specifically on cardiovascular risk communication (Waldron, van der Weijden, Ludi, Gallacher and Elwyn, 2011) found that presenting patients with individualized risk in percentages or frequencies, using graphical representation and short timeframes, was best for eliciting behavior change. However, this review focused on cardiovascular risk only and did not attempt to explore whether theory-based interventions were more effective than atheoretical work in eliciting behavior change or whether certain presentation details such as who delivered the risk information and whether it was simple or complex details that were given were best. If the purpose of risk communication is to lead to behavior change such as screening uptake, then theoretical work, such as social cognition models designed to inform behavior change interventions may be useful in designing risk communication interventions.

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**Uptake of screening for Type 2 diabetes risk in General Dental Practice;
an exploratory study**

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Key words – diabetes, risk, screening, dentistry

Abstract:**Aim:**

The objective of this study was to determine dental patients' uptake of two preliminary screening tools for risk of diabetes (the Finnish Diabetes Risk Score –FINDRISC- and HbA1c fingerprick testing) in general dental practice, and to determine the number of patients at risk of type 2 diabetes (T2D) based on the results of these screening tests.

Methods:

Patients aged 45 and over, who did not already have a diagnosis of diabetes, visiting primary dental practitioners for routine appointments in London (N= 244) and Staffordshire (N=276), were offered the chance to be screened for diabetes risk using the FINDRISC a self-report screening tool to assess risk of development of diabetes in the next 10 years. If a patient's score showed them to be at risk, they were offered an instant HbA1c finger-prick test to further screen for possible type 2 diabetes where they were given their result instantaneously. Patients found to be at risk on either screening test, were referred to their GP for formal diagnostic testing.

Results:

N=1035 patients eligible for inclusion were asked to take part. N=520 patients consented to screening. Of these, N=258 patients (49.6%) were found to be at risk of developing diabetes based on FINDRISC scores and were referred to the GP for further testing and offered a further screening finger-prick blood test at the dental practice. N=242 (93.8% of those offered the test) accepted the on the spot finger-prick test. On this A1c test, N=118 had a result of 5.7% or higher, indicating increased risk for diabetes. Of the N=258 who were referred to their GP for formal diabetes testing, N=155 (60%) contacted their doctor. There was a significant association between the number of 'at risk' screening results a person received and whether or not a patient contacted their GP ($p<0.0001$). The odds of patients contacting the GP was 3.22 times higher if they were referred with two positive diabetes risk results (positive FINDRISC, positive HbA1c) rather than just one (positive FINDRISC, negative HbA1c).

Conclusions:

The study demonstrates a two-step method of diabetes screening that appears to be acceptable by dental patients, a sizeable proportion of whom were identified as at risk of developing diabetes, and the majority following the recommendation for further testing with their GP. Whilst the majority followed the recommendation for further testing with their GP, patients were 3 times more likely to contact their GP if they received a positive risk result on both screening tools.

Introduction

Diabetes is an illness characterised by chronically elevated levels of blood glucose concentration, a condition known as hyperglycaemia, for which there is no known cure. T2D has become a huge burden for the adult population with ever-increasing prevalence (Wild, Rolgic, Green, Sicree and King, 2004), however, there is no screening programme policy in place in the UK despite the fact that detecting diabetes early on is key to health outcomes (Harris and Eastman, 2000).

Screening for diabetes can potentially allow for early diagnosis and treatment, which can prevent diabetes-related complications (Marre & Travert, 2010). Although screening for disease can sometimes have adverse effects on an individual, screening for diabetes has been shown not to have any long-term adverse effects (Adriaanse, Snoek, Dekker, Spijkerman, Nijpels, Twisk et al. 2004). Therefore, it is suggested that screening for diabetes is essential to identify diabetes and importantly, its precursors, earlier and more efficiently.

Diabetes can be screened for using a variety of methods; in addition to traditional diabetes screening methods such as the Oral Glucose Tolerance Test (OGTT) where patients are required to consume glucose and then have blood samples taken afterward to determine how quickly the glucose is cleared from the blood, the use of HbA1c as a measure of glycaemic control over the past 12 weeks, has also been recommended as a viable means of diagnosing diabetes (Saudek et al, 2008). An invasive test, as it requires a blood sample, HbA1c testing does not require fasting or restriction to certain times of the day to be measured so in many respects it is easier to carry out than an OGTT. Furthermore, whilst traditionally HbA1c tests require laboratory facilities to take place, the recent introduction of point of care measurement through finger prick devices has made the measurement of A1c more accessible (Wensil, Smith, Pound & Herring, 2003; Sicard & Taylor, 2005). As an alternative to a blood test, the FINDRISC is a non-invasive screening tool that provides a measure of the probability of developing type 2 diabetes over the next 10 years (Lindstrom, Louheranta, et al. 2003). It is a brief questionnaire consisting of eight questions about variables correlated with the risk of developing diabetes: age; body mass index; family history of diabetes; waist circumference; use of anti-hypertensive medication; history of elevated blood glucose; meeting the criterion for daily physical activity and daily consumption of fruit and vegetables. FINDRISC has been used successfully as a screening tool for diabetes (Tankova, Chakarova, Atanassova, & Dakovska, 2011) and its reliability and validity have been clearly established (Janghorbani, Adineh & Amini, 2013; Gomez-Arbelaez, Alvarado-Jurado, Ayala-Castillo, Forero-Naranjo, Camacho, Lopez-Jaramillo, 2015).

Screening for diabetes can be carried out in various health settings (Howse, Jones & Hungin, 2011). As diabetes is recognised as a significant risk factor for serious, progressive periodontal disease (Southerland, Taylor & Offenbacher, 2005) and as periodontal disease may contribute to the progression of impaired glucose tolerance to diabetes (Andersen, Flyvbjerg, & Holmstrup, 2007), the dental setting seems like a plausible context for the identification of people at risk for diabetes.

Some recent research from the US has examined the usefulness of screening for diabetes in dental settings. Four US studies [Genco et al. (2014); Greenberg et al. (2015); Bossart et al. (2015) and

Herman et al. (2015)] reliably supported the notion that screening for pre-diabetes and diabetes using a combination of invasive and / or self-report methods was feasible, acceptable to patients and the dental team and effective in US dental offices.

In the single UK study carried out in GDPs in London using a self-report risk measure developed in the UK (Wright, Muirhead, Weston-Price & Fortune, 2014), it was found that notwithstanding the manpower challenges facing dental teams and the fairly low uptake of further screening by patients, the identification of diabetes in dental practices was possible. One explanation for the low uptake of further diagnostic testing in this study could be the fact that patients tend to judge the severity of the illness by cues such as the complexity of the diagnostic tool used. In the case of diabetes in particular, previous work (Parry, Peel, Douglas and Lawton 2003) showed that diabetes patients used their diagnosis journey to judge how serious their diabetes was; the more complex the diagnosis, (where for e.g. the diagnosis was made by a hospital consultant rather than a GP) the more serious patients thought was their diabetes.

On the basis of these findings, we reasoned that supplementing a self-report diabetes risk assessment with a more invasive, instant HbA1c blood test might improve the uptake of further formal GP testing. At the same time, we wished to explore the acceptability of such a double-screening method in UK dental practices

Thus the objective of this study was to determine the uptake of diabetes screening in dental patients, using FINDRISC and HbA1c information as preliminary screening tools, and to determine the proportion of patients who attend their GP for further, formal diabetes diagnostic testing.

Methods

Participants meeting the inclusion criteria were recruited from two General Dental Practices in London and Staffordshire, UK. Dental patients who were aged 45 and over, could speak fluent English and had no diagnosis of diabetes or pre-diabetes were sent an invitation letter with information explaining the nature of the research. These inclusion criteria were set due to an increase in diabetes risk with age and because the risk questionnaire had been validated in English.

On arrival, participants wishing to take part met with the researcher, gave informed consent and completed a demographics and FINDRISC questionnaire. The participant then saw the dentist for their routine appointment. At the end of their appointment, the participant met with the researcher who gave the participant their result of the FINDRISC. Participants with a score of < 10 on the FINDRISC were debriefed about their risk result, reassured and thanked for their participation. Patients with a score of ≥ 10 on the FINDRISC were told about their increased risk and offered an HbA1c finger-prick test to explore their risk further. Participants receiving the blood test were given the result instantaneously, with an explanation of its meaning. Regardless of acceptance of the HbA1c or test the A1c test result, all patients with a FINDRISC of >10 were advised by the researcher to visit their GP for a formal diagnostic test via verbal advice and written information. All participants' GPs were informed of their participation through a standard letter from the dental practitioner and researcher, and a formal diagnostic test was recommended where results indicated

the need for this. One month after participants took part in screening, they were contacted by telephone by the researcher to find out if they had been to their GP for formal diagnostic testing as recommended. If they had not already been, a second call was made one month later to find out the outcome. Finally, three months after the initial screening was conducted, patients' GPs were contacted through a standard letter and reply slip to find out if the patient had been in contact to further confirm the patients self-report or to confirm the outcome for patients unable to be contacted.

Results:

Figure 1 shows the flow of participants through the study.

----- Fig 1 about here -----

N=3700 NHS and private patients had a dental appointment during the 118 day recruitment period. N=2109 patients were excluded as they were either under 45 years of age (n=1888), did not speak fluent English (n=59), or already had diabetes/ pre-diabetes (n=162). A further 556 potential participants were not asked to take part as they either did not attend their appointment (n=121) or practically could not be tested by the single researcher (n=435).

Of the remaining 1035 patients, 520 (50.2%) consented to participate and completed the FINDRISC screening questionnaire. Five hundred and fifteen patients refused to participate in the study. The main reasons for refusal were, a recent blood glucose test, a recent health check-up such as the Well Man's Check arranged through the GP, dental pain and fear, and lack of interest in the research.

Two hundred and sixty two (N=262) participants scored below the cut off score of 10 on the FINDRISC questionnaire, and therefore were not offered any further screening. N=258 patients were found to be at risk of developing diabetes based on the current recommended FINDRISC cut off score of 10, and so were offered the further screening test, and advised to visit their GP for formal diagnostic testing. The majority of participants (n=247, 47.5% of those who took part) fell into the slightly elevated risk category, whilst N=101 (19.42% of those who took part) fell in the low risk category and N=172 (33%) were seen as having a moderate, high or very high risk of developing diabetes. Table 1 outlines the number of participants by risk score category on the risk questionnaire.

-----Table 1 about here -----

Of the N=258 found to be at risk of developing diabetes on the FINDRISC, the majority (N=242, 93.8%) accepted and received the further screening HbA1c test. These A1c test results are shown in Table 2 that follows.

----- Table 2 here -----

On this A1c test, 10 participants (4.13% of those who took the test) had a result of $\geq 6.5\%$, 108 participants (44.6% of those who took the test) had a result of between 5.7% and 6.4%, whilst 124 participants (51.24% of those who took the test) had a result of less than 5.7%.

Of the N=258 participants who were advised to visit their GP for formal diabetes testing, N=155 (60%) contacted their doctor regarding an appointment for further testing.

There was a significant association between the number of 'at risk' screening results a person received and whether or not a patient would follow recommendation and contact their GP ($\chi^2 (1) = 16.84, p < 0.0001$). Furthermore, the number of positive risk scores significantly influenced GP contact; patients were more likely to contact their GP if they had received two positive risk scores. The odds ratio of patients contacting the GP was 3.22 times higher if they were referred with two positive risk results (both a positive FINDRISC and positive HbA1c risk result) as opposed to just one (a positive FINDRISC but negative HbA1c).

Discussion

The objective of this study was to determine the uptake of dental patients using FINDRISC and HbA1c information as preliminary screening tools in screening for possible diabetes, and determine the number of patients at risk of diabetes.

As with the previous US and UK studies, the current study found that many dental patients were happy to participate and receive one or more diabetes screening tests offered to them. The results showed a successful uptake of dental patients for diabetes screening, with 50% of eligible patients consenting to participate. The refusal rate of N=515 was higher than the figure stated in Wright et al. (2014). Several reasons for this can be offered, such as, that potential participants are much more likely to take part in research that is concerned with an issue which is particularly relevant to the participants' lives, overall there is a decline in willingness to participate in scientific studies in Western countries, which may hold little immediate benefit to the participant (Galea & Tracy, 2007). Finally, participants may be wary of committing their involvement to research that is likely to take up a substantial amount of their time given how scientific research has become increasingly demanding over the last decade (Galea & Tracy, 2007).

Almost half of dental patients screened using the FINDRISC were found to be at risk of developing diabetes based on the current cut-offs. In line with previous work, the majority of participants fell into the slightly elevated risk category, with a personalised risk score of between 7 and 11 (Costa et al. 2013). Wright et al. (2014) found that 84% of dental patients screened had at least some increased level of risk of diabetes, based on the NICE guidance tool which included a risk questionnaire and BMI measurement. Our sample, based on the risk questionnaire alone showed a similar result; that N=419 (81%) of the 520 participants had some level of elevated risk of diabetes.

When looking at the results the point of care HbA1c measure, N=118 (45% of those taking the test) had a score of $\geq 5.7\%$ suggesting a risk of pre-diabetes and diabetes. Compared to 30% found by Herman and colleagues (Herman et al. 2015) and 40% in the participant sample of Genco and colleagues (Genco et al. 2014), our result is slightly higher, probably because only those with FINDRISC score over 10 were offered the HbA1c test. The majority of participants (94%) scoring 10 or higher on the FINDRISC were happy to have their HbA1c measured by the researcher. Therefore these results support the notion that dental patients are happy to be screened for diabetes using a combination of a simple questionnaire and a more invasive finger-prick blood test.

Crucially, a high proportion (60%) of those advised to visit their GP for further formal diabetes testing followed this advice and contacted their GP. This is a much more promising result than found previously. For instance, Wright et al (2014) reported that only 20% of patients identified as at risk of developing diabetes attended their GP. Genco et al (2014) reported that 35% attended their GP for follow up; though there was a significant difference in follow-up rates between patients referred from a community health centre where over 78% attended their GP compared to only 21% from private dental offices.

There are of course limitations to this study that should be considered. There was a discrepancy in the numbers of patients who were eligible to participate and those who took part, not only because there were patients who refused to participate, but because the method of data collection meant that some patients who were eligible to participate were missed because the researcher was not able to approach every potential participant before their appointment with the dentist. Therefore, the number of dental patients who would have participated might be different in a study using more than one researcher recruiting and testing at any one time. This also has implications for the adoption of diabetes screening in the dental practice. Recruitment and screening in the current study was carried out by a psychology researcher and as such, the manpower and time issues that were raised in the Wright et al study still need to be considered before these findings are taken to routine dental care.

HbA1c was only measured in those participants who scored highly enough on the FINDRISC questionnaire to qualify for the further screening test. As the risk questionnaire is mainly self-report, there is always a chance that those participating may exaggerate their answers and therefore the questionnaire may not give a true representation of a person's risk. Thus, those in our sample who did not score highly enough on the FINDRISC to qualify for the second screening test; the HbA1c test, may well have had an elevated HbA1c score, therefore increasing the percentage of overall participants with a high risk HbA1c score of $\geq 5.7\%$.

In conclusion, this study demonstrates a method of diabetes screening that shows an acceptable rate of uptake by dental patients. It demonstrates a relatively high number of patients 'at risk' of developing diabetes and that the majority of these follow up their screening result with further tests with their GP.

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Tables and Figures

Table 1: Number of participants by FINDRISC risk score category.

FINDRISC category	No. of participants
< 7 LOW risk	101(19.42%)
7-11 SLIGHTLY ELEVATED risk	247(47.5%)
12-14 MODERATE risk	108(20.77%)
15-20 HIGH risk	63(12.12%)
>20 VERY HIGH risk	1(0.2%)
TOTAL:	520
FINDRISC score of <10 as current cut off for further screening	262(50.38%)

Table 2: Number of participants by HbA1c score.

HbA1c cut off category	N
<5.7 %	124
5.7 – 6.4 %	108
≥6.5 %	10

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SE1 9RW

Introductory Letter
REC number: 13/WM/0265
(Version 1, 14.03.13)

Dear.....

We are writing to ask you to consider taking part in a novel research project currently running in our practice. The project is run in partnership with our colleagues at the Dental Institute, King's College London.

The project looks to screen our patients for diabetes. As you may know, diabetes is a serious illness which often remains undiagnosed as it does not normally present with obvious symptoms. Detected early, the illness can be managed successfully and lead to better long-term health outcomes. This is a service we are offering to all our patients who are over 45 years of age, do not already have diabetes and are fluent in English. This service is currently free of charge. We are very much hoping that you will take the opportunity to help with the work and get yourself screened.

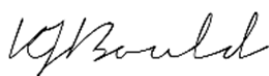
We have attached an Information sheet which tells you more about the study. If you do decide to take part, **please would you kindly attend your next appointment 15 minutes early**. This is to allow you time to meet with the researcher doing the screening and have any questions about the research answered.

Thank you for your time in reading this.

Yours,



Dr. Amit Jilka
(Dental Surgeon, BDS, MJDF, RCSEng)



Miss Kathryn Bould
(Researcher)

Appendix 4: Interview Schedules

Proposed Interview Questions for General Dental Practitioners

1. What do you think about screening for diabetes in general? Is it a good or bad idea? Why?

What do you think about screening for diabetes in dental practices? Is a good or bad idea? Why?

2. What did you think about the screening programme we conducted at your practice?
3. What do you think about using a self-report questionnaire to assess risk of developing diabetes in the first instance?
4. What do you think about using a finger-prick blood test to screen for diabetes?
5. Do you think that this screening programme could be incorporated into your routine practice? If not, why not?
6. What would you change about the procedure that we adopted?

Proposed Interview Questions for Participants

1. What do you know about diabetes?
2. How serious do you think diabetes is?
3. Do you think that screening for diabetes is worthwhile?
4. Before being offered the opportunity to be screened for diabetes, did you think you were susceptible to the condition? If yes why? If not why not?
5. What did you think of the offer to be screened for diabetes at your dental appointment? What were your initial thoughts?
6. What was your impression of the self-report questionnaire which assesses your risk of developing diabetes in the future?
7. After being told your result from the questionnaire, did this change how you felt about your risk? In what ways?
8. *(for any participants declining the option for the second screening finger-prick test)* Was there any particular reason you decided not to have the second screening (the finger prick) test that we offered you?
9. *(for participants who had the finger prick test)* What made you decide to have the second finger-prick test that we recommended you to have?
10. How did the result of this test make you feel?

11. *(for participants identified as low risk on the FINDRISC)* How did you feel after being told you were currently at a low risk of developing diabetes in the future? Have you talked to a health-care professional about this since?
12. *(for participants identified as high risk on the FINDRISC alone or on the finger-prick test also)* When we advised you to see your GP for diagnostic testing after initial screening at the dentist had shown you were at risk of diabetes; how did you feel? Did you feel more or less susceptible to diabetes than you did before screening?
13. Did you see your GP following advice to do so?
14. What made you go ahead and see your GP?
15. What do you think about the screening programme that we adopted?
16. What do you think about using a self-report questionnaire to assess risk of developing diabetes in the first instance?
17. What do you think about using a finger-prick blood test to screen for diabetes?
18. Do you have any comments about your experience that you would like to make and which we have not covered in these questions?

Study Title: The effects of screening for diabetes in the dental setting on subsequent health behaviours

REC Study Number: 13/WM/0265

Participant Identification number for this study:

Address:

.....

.....

Telephone:

Name of GP and Surgery:

Demographic Details:

Gender (*please circle*): MALE FEMALE

DOB (*dd/mm/yy*):

Type of patient (*please circle*): NHS PRIVATE

Ethnic group: Choose one option that best describes your ethnic group or background

White	Mixed / Multiple ethnic groups	Asian / Asian British	Black / African / Caribbean / Black British	Other ethnic group
1. English / Welsh / Scottish / Northern Irish / British	5. White and Black Caribbean	9. Indian	14. African	17. Arab
2. Irish	6. White and Black African	10. Pakistani	15. Caribbean	18. Any other ethnic group, please describe.....
3. Gypsy or Irish Traveller	7. White and Asian	11. Bangladeshi	16. Any other Black / African / Caribbean	
4. Any other White background, please describe.....	8. Any other Mixed / Multiple ethnic background, please describe.....	12. Chinese	background, please describe.....	
		13. Any other Asian background, please describe.....		

(*Office use only*)

Results:

FINDRISC score:

HbA1c result (if applicable):

FINDRISC Questionnaire

(Version 1, 15.03.13)

REC number: 13/WM/0265

Circle the right alternative

1. Age

- Under 45 years
- 45–54 years
- 55–64 years
- Over 64 years

2. Body-mass index (a BMI calculator will be attached to the questionnaire)

- Lower than 25 kg/m²
- 25–30 kg/m²
- Higher than 30 kg/m²

3. Waist circumference measured below the ribs (usually at the level of the navel)

MEN

- Less than 94 cm
- 94–102 cm
- More than 102 cm

WOMEN

- Less than 80 cm
- 80–88 cm
- More than 88 cm

4. Do you usually have daily at least 30 minutes of physical activity at work and/or during leisure time (including normal daily activity)?

- Yes
- No

5. How often do you eat vegetables, fruit or berries?

- Every day
- Not every day

6. Have you ever taken medication for high blood pressure on regular basis?

- No
- Yes

7. Have you ever been found to have high blood glucose (eg in a health examination, during an illness, during pregnancy)?

- No
- Yes

8. Have any of the members of your immediate family or other relatives been diagnosed with diabetes (type 1 or type 2)?

- No
- Yes: grandparent, aunt, uncle or first cousin (but no own parent, brother, sister or child)
- Yes: parent, brother, sister or own child

How useful do you think it is to use this diabetes screening questionnaire in general dental practice?
Please circle one number.

Not at all useful						Extremely useful
0	1	2	3	4	5	

FINDRISC SCORING SHEET

1. Age

0 p. Under 45 years

2 p. 45–54 years

3 p. 55–64 years

4 p. Over 64 years

2. Body-mass index (a BMI calculator will be attached to the questionnaire)

0 p. Lower than 25 kg/m²

1 p. 25–30 kg/m²

3 p. Higher than 30 kg/m²

3. Waist circumference measured below the ribs (usually at the level of the navel)

MEN

0 p. Less than 94 cm

3 p. 94–102 cm

4 p. More than 102 cm

WOMEN

Less than 80 cm

80–88 cm

More than 88 cm

4. Do you usually have daily at least 30 minutes of physical activity at work and/or during leisure time (including normal daily activity)?

0 p. Yes

2 p. No

5. How often do you eat vegetables, fruit or berries?

0 p. Every day

1 p. Not every day

6. Have you ever taken medication for high blood pressure on regular basis?

0 p. No

2 p. Yes

7. Have you ever been found to have high blood glucose (eg in a health examination, during an illness, during pregnancy)?

0 p. No

5 p. Yes

8. Have any of the members of your immediate family or other relatives been diagnosed with diabetes (type 1 or type 2)?

0 p. No

3 p. Yes: grandparent, aunt, uncle or first cousin (but no own parent, brother, sister or child)

5 p. Yes: parent, brother, sister or own child

Total Risk Score =

The risk of developing type-2 diabetes within 10 years is:

SCORE	RISK CATEGORY	
< 7	Low	estimated 1 in 100 will develop disease
7-11	Slightly elevated	estimated 1 in 25 will develop disease
12-14	Moderate	estimated 1 in 6 will develop disease
15-20	High	estimated 1 in 3 will develop disease
> 20	Very high	estimated 1 in 2 will develop disease

Your Views About Diabetes & Diabetes Screening

REC number: 13/WM/0265

(Version 1, 15.03.13)

We are interested in your own personal views of diabetes and taking a blood glucose test. Please indicate how much you agree or disagree with each of the following statements by ticking the appropriate box.

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly Disagree
1. Diabetes is a serious condition					
2. I am unlikely to have diabetes					
3. If I do not have a blood glucose test I will be able to carry on as usual					
4. If I do not have a blood glucose test I will be able to forget about the possibility of having diabetes					
5. A blood glucose test is the best way of finding diabetes early					
6. Having a blood glucose test could help prevent diabetes related complications					
7. Having a blood glucose test could help prevent diabetes related illness					
8. By having a blood glucose test I will know if I have diabetes or not					
9. Having a blood glucose test will give me a peace of mind					
10. I feel confident in my ability to go to my doctor to have a blood glucose test					
11. It would not be difficult for me to go to my doctor to have a blood glucose test					
12. Going to my doctor to have a blood glucose test would be easy for me					
13. I am discouraged from going to my doctor to have a blood glucose test because I feel unable to do so					
14. The benefits of having a blood glucose test outweigh the costs					
15. Having a blood glucose test would cause me too many problems					
16. I am discouraged from having a blood glucose test as it would take too much time					
17. Having a blood glucose test would be unpleasant					
18. Having a blood glucose test would be inconvenient					
19. Having a blood glucose test would make me anxious					
20. I am discouraged from having a blood glucose test as the results may mean I have to start changing my lifestyle					
21. I am discouraged from having a blood glucose test as the results may mean I have to start taking tablets					
22. I intend to have a blood glucose test					

23. I do not wish to have a blood glucose test					
--	--	--	--	--	--

	Very high	Fairly high	Moderate	Fairly low	Very low
1. I think my chances of having diabetes are:					

	Very frightened	Quite frightened	A little bit frightened	Not at all frightened
2. The thought of having diabetes makes me feel:				

	Very anxious	Quite anxious	A little bit anxious	Not at all anxious
3. The thought of having diabetes makes me feel:				

	Very scared	Quite scared	A little bit scared	Not at all scared
4. The thought of having diabetes makes me feel:				

	Very worried	Quite worried	A little bit worried	Not at all worried
5. The thought of having diabetes makes me feel:				

	Yes	No	Unsure
6. Have you had blood glucose test before?			

Your Views About Diabetes & Diabetes Screening

REC number: 13/WM/0265

(Version 1, 15.03.13)

**We are interested in your own personal views of diabetes and taking a blood glucose test.
Please indicate how much you agree or disagree with each of the following statements by
ticking the appropriate box.**

Subscale	Highlighted items require reverse coding	Strongly agree [1]	Agree [2]	Neither agree or disagree [3]	Disagree [4]	Strongly Disagree [5]
severity	24. Diabetes is a serious condition					
vulnerability	25. I am unlikely to have diabetes					
Rewards for maladaptive response	26. If I <u>do not</u> have a blood glucose test I will be able to carry on as usual					
	27. If I <u>do not</u> have a blood glucose test I will be able forget about the possibility of having diabetes					
Response efficacy	28. A blood glucose test is the best way of finding diabetes early					
	29. Having a blood glucose test could help prevent diabetes related complications					
	30. Having a blood glucose test could help prevent diabetes related illness					
	31. By having a blood glucose test I will know if I have diabetes or not					
	32. Having a blood glucose test will give me a peace of mind					
Self-efficacy	33. I feel confident in my ability to go to my doctor to have a blood glucose test					
	34. It would not be difficult for me to go to my doctor to have a blood glucose test					
	35. Going to my doctor to have a blood glucose test would be easy for me					
	36. I am discouraged from going to my doctor to have a blood glucose test because I feel unable to do so					
Response costs	37. The benefits of having a blood glucose test outweigh the costs					
	38. Having a blood glucose test would cause me too many problems					
	39. I am discouraged from having a blood glucose test as it would take too much time					
	40. Having a blood glucose test would be unpleasant					
	41. Having a blood glucose test would be inconvenient					
	42. Having a blood glucose test would make me anxious					
	43. I am discouraged from having a blood glucose test as the results may mean I have to I have to start changing my lifestyle					
	44. I am discouraged from having a blood glucose test as the results may mean I have to start taking tablets					
Intention	45. I intend to have a blood glucose test					

	46. I do not wish to have a blood glucose test					

		Very high [1]	Fairly high [2]	Moderate [3]	Fairly low [4]	Very low [5]
vulnerability	47. I think my chances of having diabetes are:					

		Very frightened [4]	Quite frightened [3]	A little bit frightened [2]	Not at all frightened [1]
fear	48. The thought of having diabetes makes me feel:				

		Very anxious [4]	Quite anxious [3]	A little bit anxious [2]	Not at all anxious [1]
fear	49. The thought of having diabetes makes me feel:				

		Very scared [4]	Quite scared [3]	A little bit scared [2]	Not at all scared [1]
fear	50. The thought of having diabetes makes me feel:				

		Very worried [4]	Quite worried [3]	A little bit worried [2]	Not at all worried [1]
fear	51. The thought of having diabetes makes me feel:				

	Yes	No	Unsure
52. Have you had blood glucose test before?			

Mood Questionnaire
REC number: 13/WM/0265
 (Version 1, 18.03.13)

The following list contains statements of events you may have experienced over the past week. Please circle one number for each statement, to show how frequently you experienced the event in the past 7 days.

	Rarely or none of the time (Less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5 – 7 days)
1. I was bothered by things that usually don't bother me	0	1	2	3
2. I did not feel like eating; my appetite was poor	0	1	2	3
3. I felt that I could not shake off the blues even with help from my family or friends	0	1	2	3
4. I felt that I was just as good as other people	0	1	2	3
5. I had trouble keeping my mind on what I was doing	0	1	2	3
6. I felt depressed	0	1	2	3
7. I felt that everything I did was an effort	0	1	2	3
8. I felt hopeful about the future	0	1	2	3
9. I thought my life had been a failure	0	1	2	3
10. I felt fearful	0	1	2	3
11. My sleep was restless	0	1	2	3
12. I was happy	0	1	2	3
13. I talked less than usual	0	1	2	3
14. I felt lonely	0	1	2	3
15. People were unfriendly	0	1	2	3
16. I enjoyed life	0	1	2	3
17. I had crying spells	0	1	2	3
18. I felt sad	0	1	2	3
19. I felt that people disliked me				

	0	1	2	3
20. I could not get 'going'	0	1	2	3

Appendix 11: CES-D Questionnaire Scoring

CESD: The following list contains statements of events you may have experienced over the past week. Please circle one number for each statement, to show how frequently you experienced the event in the past 7 days.

	Rarely or none of the time (Less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5 – 7 days)
1. I was bothered by things that usually don't bother me	0	1	2	3
2. I did not feel like eating; my appetite was poor	0	1	2	3
3. I felt that I could not shake off the blues even with help from my family or friends	0	1	2	3
4. I felt that I was just as good as other people	0	1	2	3
5. I had trouble keeping my mind on what I was doing	0	1	2	3
6. I felt depressed	0	1	2	3
7. I felt that everything I did was an effort	0	1	2	3
8. I felt hopeful about the future	0	1	2	3
9. I thought my life had been a failure	0	1	2	3
10. I felt fearful	0	1	2	3
11. My sleep was restless	0	1	2	3
12. I was happy	0	1	2	3
13. I talked less than usual	0	1	2	3
14. I felt lonely	0	1	2	3
15. People were unfriendly	0	1	2	3
16. I enjoyed life	0	1	2	3
17. I had crying spells	0	1	2	3
18. I felt sad	0	1	2	3
19. I felt that people disliked me	0	1	2	3
20. I could not get 'going'	0	1	2	3

Scoring: Reverse the positive items and sum up total score across 20 items.

Participant Information Sheet

The effects of screening for diabetes in the dental setting on subsequent health behaviours

REC Study Number: 13/WM/0265

(Version 5, 31.07.13)

You are being invited to take part in a research study carried out as part of an educational project for a PhD qualification. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Please ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

The study is only open to people who can read English. If you cannot read English proficiently, or if you have already been diagnosed with diabetes, please ignore this letter.

What is the purpose of the study?

Type 2 diabetes develops when the body does not produce enough insulin to maintain a normal blood glucose level, or when the body is unable to effectively use the insulin that is being produced.

The illness does not present with clearly identifiable symptoms and as such, remains largely under-diagnosed. Type 2 diabetes and oral health are related. Diabetes is known to adversely affect people's oral health. Detecting diabetes early on, is key to better health and oral health outcomes.

In this study we are looking at the feasibility of using a brief, self-report questionnaire and, where appropriate a finger-prick and a saliva test as preliminary screening tools for type 2 diabetes in general dental practice. We are also interested in the effects of these tests on patients' subsequent health behaviours, that is, why following the receipt of a screening test result some people follow up the result with further diagnostic testing as advised and others do not, and on the relationship between diabetes risk and oral health status.

Why have I been chosen?

We are asking adult patients attending for a routine dental appointment who are over the age of 45, who are fluent in English and who do not have a diagnosis of diabetes, if they would like to take part. The records kept by your dentist suggest that you meet these criteria and this is the reason you are being approached for recruitment into the study.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part will not affect the standard of care you receive. If you withdraw from the study, any data collected from you will not be retained or used in the study.

What will happen to me if I take part?

You will need to attend your usual dental appointment 15 minutes early and allow up to around 20 minutes after your dental appointment. Once you arrive the researcher will answer any questions you may have about the study. Then, if you are happy to help us with this research you will be asked to sign the consent form.

There are five components to this study and you can **choose to take part in one, more or all of them.**

Part 1: At the dental practice, we will give you a simple, brief questionnaire to complete known as the Finnish Diabetes Risk Score (FINDRISC). The questionnaire asks some very simple questions e.g. about your family history of diabetes and your diet. One of the questions is about your current Body Mass Index (BMI). To answer this, the researcher will collect weight and height information from you so she can work out your current BMI.

This questionnaire will take about 5 minutes to complete and has been shown to predict people's risk of developing diabetes or 'pre-diabetes', a condition related to a high risk of future diabetes.

Part 2: We will also ask you to give us a small sample of your saliva, which we will collect in a plastic tube. We will send this sample to our labs at King's College London along with the samples of other patients for analysis; scientists will use this sample and information from your dental history to examine the link between risk of diabetes and oral health. With your consent, we will store your saliva sample for use in other ethically approved research projects.

You will then see your dentist for your appointment as usual. During this time, the researcher will use your FINDRISC questionnaire answers to work out your risk of developing diabetes or 'pre-diabetes'.

After your dental appointment, we would like you to stay for up to 20 minutes. The researcher will tell you your personal risk from the result of the questionnaire and if at risk, discuss sources of support with you.

Part 3: Based on the questionnaire result, you may be offered a further screening test to further assess your risk of diabetes more precisely.

This will involve taking a small drop of blood from your finger (finger-prick test). This test will give us information about your blood sugar levels over the past 8-12 weeks and can serve as an indication of whether you have diabetes or 'pre diabetes'. **Please note that this screening test does not totally rule out the possibility that you may have diabetes or may develop diabetes in the future.** If you are shown to be at risk of developing diabetes from either the results of the questionnaire or the finger-prick test, you will be advised to see your GP for a formal diagnostic test. We will write to your GP to explain that we have advised you to see them. This part of the research will take about 10 minutes to complete.

Part 4: If you are shown to be at risk of diabetes on either of the screening measures, you will be asked to fill in some additional, short questionnaires. There are no right or wrong answers to these questionnaires, they simply ask about your thoughts and feelings about diabetes and your current mood. They will take about 10 minutes to complete.

You can then leave the dental practice.

If you were advised to see your GP for further diabetes testing, we will contact you one month after this dental appointment by phone, to ask if you went to see your GP following the advice to do so. If you haven't sought further testing from your GP, we will remind you to do so, and contact you again by phone one month later to see if you have done so. Finally, three months after your initial dentist appointment, we will contact your GP to see if you attended for further diabetes testing, and to find out the outcome of any tests conducted.

The reason we ask you to visit your GP for a diabetes diagnostic test if found to be at risk for diabetes in our screening tests here is that screening tests only measure how much at risk someone is, rather than provide a firm diagnosis. A single, on the spot, blood test may not be reliable and might not rule out the possibility that you may have or develop diabetes in future, so it is important that you follow up your screening results with a visit to your GP, if found to be at risk.

Part 5: You may be invited at a later date to share your views of the diabetes screening experience you received and to explore the reasons why you decided to take part and why you did or did not attend for further screening at your GP if appropriate. This will be done over the telephone.

What are the possible benefits of taking part?

There are no particular individual benefits in taking part in this study, other than the possible identification of risk of developing diabetes which can lead to a subsequent early diagnosis of diabetes. However, we hope that by taking part you will learn more about your current risk of developing diabetes, which may help you to maintain good health.

What if there is a problem?

We will ask your permission to contact your GP to inform them of your taking part in this study. We will also ask your permission to inform your GP of your results from the screening tests. If we are concerned by any of these results, we will write to your GP immediately to inform them of this concern so that your GP may follow up these results as appropriate.

If you have a concern about any aspect of this study, you should ask to speak with the researcher, or any of the research team, who will do their best to answer your questions (see contact details below).

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you will have your name and address removed so that you cannot be recognised from it. All questionnaires will be stored securely. The data collected will be made available for statistical purposes, however; your data will not be identifiable. With your permission, however, we will write to your GP to tell them that you have taken part in this research and whether the screening measures have told us that you might be at risk of developing diabetes or pre-diabetes. This is routine practice for patients taking part in NHS research.

What will happen to the results of the research study?

The data we collect from all patients will be analysed and presented in peer-reviewed conferences and scientific journals. Only group data will be presented. We hope that this research will help us understand our patients better and tailor our information and treatment to best meet each patient's needs. If you wish to have information regarding the results of this study, these will be available to you upon request at completion.

Who has reviewed the study?

All research in the NHS is scrutinised by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the National Research Ethics Service Committee West Midlands- Black Country. Scientists from Bayer, the pharmaceutical company have also reviewed the study. Bayer, the pharmaceutical

company, are contributing towards some of the costs of running this study. Bayer are interested in the feasibility and uptake of screening for diabetes using some of their new equipment in a novel setting i.e. in the dental clinic.

What if I have concerns or complaints?

If you have any concerns you should raise these with a member of the research team as soon as possible. You can also contact the person responsible for the practice complaints procedure. If you are an NHS dental patient you can contact the local Patient Liaison and Advisory Service (PALS) for advice. Never feel embarrassed to ask questions as we want to support you, and it may help us to improve future studies.

Contact your nearest PALS:

Floor 1, Morston House, The Midway, Newcastle-under-Lyme, Staffordshire. ST5 1QG.

Telephone: 0800 783 2865. Email: customerservice@ssotp.nhs.uk

Contact details for further information

If you have any questions or would like to obtain further information about this study, please contact:-

Kathryn Bould, BSc, MSc (PhD Researcher) at: Unit of Social and Behavioural Sciences, King's College London, Floor 18, Tower Wing, Guy's Hospital, London SE1 9RW. Telephone: 07816 582089. Email: kathryn.bould@kcl.ac.uk or

Dr. Koula Asimakopoulou, Senior Lecturer in Health Psychology and HCPC - Registered Health Psychologist, Unit of Social and Behavioural Sciences, King's College London, Floor 18, Tower Wing, Guy's Hospital, London SE1 9RW. Telephone: 0207 848 5145. Email: koula.asimakopoulou@kcl.ac.uk.

Thank you for considering this study



Study Title: The effects of screening for diabetes in the dental setting on subsequent health behaviours

REC Study Number: 13/WM/0265

(Version 3, 02.05.13)

Patient Identification Number for this study

Name of Researchers: Miss Kathryn Bould, Dr. Koula Asimakopoulou, Professor Stephen Dunne, Dr. Suzanne Scott and Professor Francis Hughes.

PLEASE INITIAL BOX

1. I confirm that I have read and understand the Participant Information Sheet for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I agree to the processing of my personal information for the purposes explained to me. I understand that such information will be handled in accordance with the terms of the Data Protection Act 1998. ☐
4. I understand that my dental notes and data collected from this study may be looked at by responsible individuals/regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐
5. I understand that you will contact my GP to inform them of my taking part in this research. I agree to you discussing any results from this study with them. ☐
6. I agree that my saliva sample can be stored by the research team pending ethical approval for use in further research projects. ☐
7. I agree that the project named above has been explained to me to my satisfaction and that I agree to take part in the above study. I have read the notes and the information sheet and understand what the research involves. ☐

I would / would not (delete as appropriate) like to receive a copy of the results of the study once they are finalised.

.....
Name of Participant

.....
Date

.....
Signature

I confirm that I have carefully explained the nature, demand and the foreseeable risks (where applicable) of the proposed research to the volunteer.

.....
Researcher

.....
Date

.....
Signature

Appendix 14: Procedure Script

Study Procedure Script

Hi, my name is (show badge), I work for KCL as(position) we are approaching people today to see if they are willing to help us with some research we are conducting looking at screening for diabetes when attending for dental appointments.

Can I tell you a little bit more about it to see if this is something you may be interested in helping us with??

YES NO —————→ *No problem, thank you for your time.*



Great, can I just check you are aged 45 or over and you are not diabetic?

YES NO —————→ *Unfortunately, you do not meet the study criteria, but thank you for your time.*



The study we are conducting should take between 15 -30 minutes, which might seem like a long time however within this time, we will assess your risk of developing diabetes and I will be able to give you your screening test outcome whilst you are here at the dental practice.

Give participant the information sheet

The reason we are conducting this research is because diabetes and oral health are related, in that, diabetes can affect oral health in many ways, therefore, early detection is important for better (oral) health outcomes.


We reason we are here is to look at the feasibility of screening for diabetes using three different methods (a simple questionnaire, a saliva sample and a finger-prick blood test) and we are interested in how the result of the screening tests affects health behaviours (who you talk to about it, what you do about it).

You don't have to take part; it won't change the dental care you receive today or at any time in the future. If you do decide to take part, you can withdraw at any time and everything will be kept confidential. I've got an information sheet for you to read (in case you didn't get a chance to look at the one sent to you in the post) which describes the study in detail which should cover any questions you may have. It's got the contact details detail on the last page too in case you need them for future reference.

If you have a look at the info sheet you'll see the study has 5 parts which you can choose to take part in one, or more, or all of:

- *Firstly, there is a questionnaire to assess personal risk of developing diabetes,*
- *We will ask you to provide for a saliva sample,*
- *Based on the result of the questionnaire, you may be offered a further screening test to assess risk...this is a quick and easy finger-prick blood test,*
- *We will ask you to complete two further questionnaires asking about your thoughts on diabetes and your mood.*

- We may ask you at a later date to have a chat over the telephone about your experience today. Does this sound like something you would be interested in?

YES **NO**  No problem, thank you for your time.



Thank you.

Give participant the consent form.

If you could just have a final look through the information sheet and then read through and sign the consent form just to confirm that you are happy to participate and that I've given you all the information.

Participant signs the consent form.

Here's the first questionnaire for you to complete, this is a validated diabetes screening tool called the FINDRISC questionnaire which assesses your risk of developing diabetes. If you could just stand up, we'll complete some of the questionnaire together by taking your height and weight measurements to calculate your BMI, and your waist circumference.


Measure participants' height against wall measure, ask them to stand on the scales to measure their weight, and use the separate tape measure to take their waste circumference.

If you would like to take a seat again and just complete Q1 and questions 4-8 and the additional question at the bottom please

Calculate BMI using the chart provided whilst participant completes the questionnaire.

Take completed questionnaire from participant and hand them the saliva tube.

Ok, whilst I score your answers, would you please spit into this tube as much as you can or until I ask you to stop?

YES **NO**  No problem, if you bear with me then whilst I score your answers and assess your risk.



Thank you.

Score FINDRISC using the FINDRISC score sheet provided.

If score is <10 select the low risk personalised risk sheet; if score is ≥10, select the high risk personalised risk sheet.

Write the score on the personalised risk sheet, and the category, according to the FINDRISC score sheet.

Take saliva sample from the participant, put the lid on, and write the participant number on the tube.

The FINDRISC questionnaire is a validated screening tool to assess the probability of developing diabetes over the next 10 years.

Hand the personalised risk sheet to the participant.

Your score on the FINDRISC questionnaire is(score). This means that from the answers you gave, your personal risk of developing diabetes in the next ten years is(category) which mean that about 1 in..... (see risk category on scoring sheet) will develop the disease.

It is currently recommended that if a person scores 10 or higher on this questionnaire, they should have further screening tests for diabetes.

FINDRISC score <10

FINDRISC score ≥10

So what does this mean for you?

From this, we **DO NOT** recommend a further screening test to assess your risk of developing diabetes at this current time

Your answers from the questionnaire suggest that your current lifestyle factors do not increase your risk of developing diabetes in the next 10 years.

However, it is important to note that if your answers to the questionnaires change in the future, your risk of developing diabetes could change. If you are concerned about your risk of diabetes changing in the future, you should see your GP.

Thank you for taking part. We will write to your GP just to let them know what we've done today.

As I mentioned the contact details should you need them are at the bottom of the information sheet.

We may contact you in the near future just to ask you about your experience today.

So what does this mean for you?

From this, we **DO** recommend a further screening test to assess your risk of developing diabetes.

The test we are recommending requires a small droplet of blood from your finger in order to get a measure of your HbA1c; that is a measure of your blood glucose level over the last 2-3 months. The kit we are using provides us with a fast and easy way to get accurate A1C results rather than sending your blood sample off to the lab for testing. This means we can give you the result now. To get the blood, we will prick your finger to get just a small drop of blood, and this should just feel like a scratch.

Would you like to have the finger-prick blood test?

Follow infection control policy when administering finger-prick blood test.

Once, we've got the blood sample, the machine will take five minutes to return the result.

Follow kit instructions to administer the test.

Whilst waiting for result, administer CES-D and EPPM questionnaire.

Whilst we wait for the result to come back, would you mind just completing 2 questionnaires about your mood and thoughts on diabetes?

Once result is returned, write result on personalised risk sheet

HbA1c result:

YES

NO

No problem.

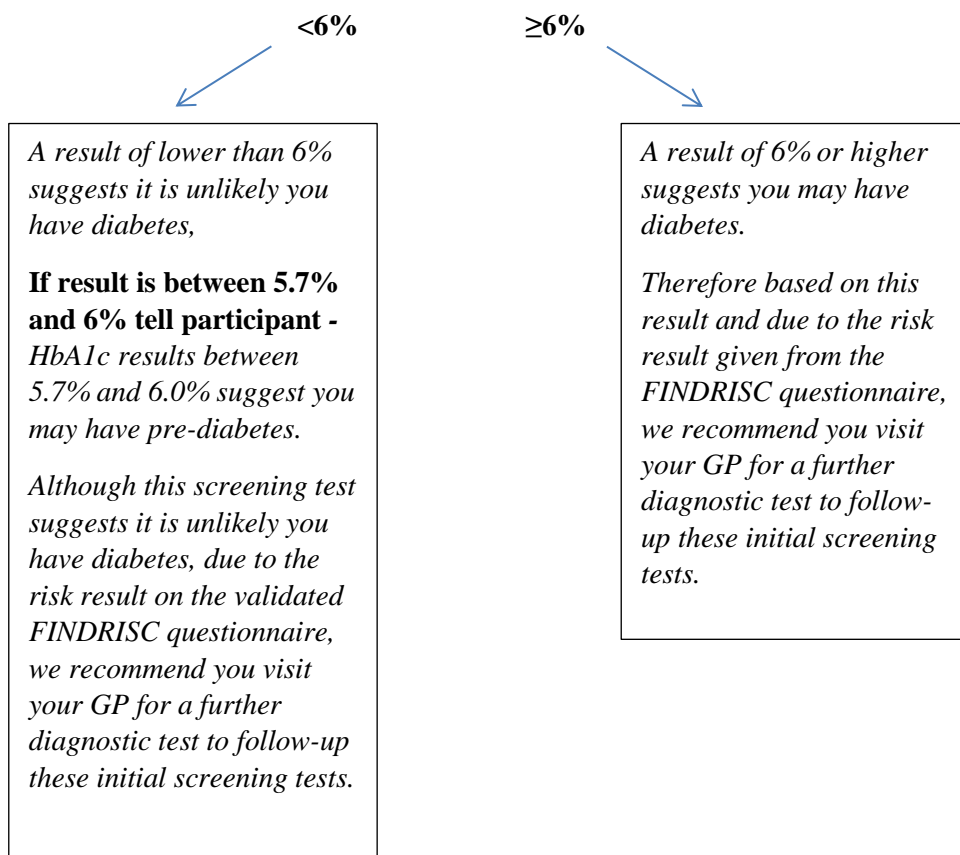
However, we do recommend you visit your GP for further testing due to your high risk score on the FINDRISC questionnaire.

Would you please complete 2 short questionnaires before you go? There are no right or wrong answers and this should only take about 5 minutes to complete.

If not, ask participant to complete at home and return to us in the freepost envelope provided.

We will write to your GP to let them know what we've done today and what we recommend.

Thank you for taking part.



We will write to your GP just to let them know what we've done today and what we've recommended.

*As I mentioned the contact details should you need them are at the bottom of the information sheet.
We may contact you in the near future just to ask you about your experience today.*

Ensure demographics sheet is completed before patient leaves.

After the participant has left the surgery:

Write results on appropriate first GP letter and Send letter with participant information sheet

Score CES-D – if score 16 or more, send GP referral letter (CES-D)

If HbA1c is 6% or higher, send GP referral letter (HbA1c)

Complete information from dental records sheet

Complete log sheet

Enter follow up calls and follow up GP letter 'triggers' in the diary

PERSONALISED RISK OF DEVELOPING DIABETES

REC number: 13/WM/0265

(Version 1, 15.03.13)

ID Number

You have completed the FINDRISC questionnaire which provides a measure of the probability of developing diabetes over the following 10 years.

YOUR SCORE FROM THE FINDRISC QUESTIONNAIRE IS:

Your answers from the FINDRISC questionnaire suggest that your PERSONAL RISK of developing diabetes in the next 10 years is:

It is recommended that individuals with a score of 10 or higher on this questionnaire should have further screening for diabetes.

Based on this information we DO NOT RECOMMEND a further screening test to assess your risk of developing diabetes at the current time.

Your answers from the questionnaire suggest that your current lifestyle factors do not increase your risk of developing diabetes in the next 10 years.

However, it is important to note that if your answers to the questionnaires change in the future, your risk of developing diabetes could change.

If you are concerned about your risk of diabetes changing in the future, you should see your GP.

More information about diabetes can be found on the UK's leading diabetes charity, Diabetes UK website: <http://www.diabetes.org.uk/>

PERSONALISED RISK OF DEVELOPING DIABETES

REC number: 13/WM/0265

(Version 1, 15.03.13)

ID Number

You have completed the FINDRISC questionnaire which provides a measure of the probability of developing diabetes / prediabetes over the following 10 years.

YOUR SCORE FROM THE FINDRISC QUESTIONNAIRE IS:

Your answers from the FINDRISC questionnaire suggest that your PERSONAL RISK of developing diabetes in the next 10 years is:

It is recommended that individuals with a score of 10 or higher on this questionnaire should have further screening for diabetes.

Based on this information we RECOMMEND a further screening test to assess your risk of developing diabetes.

The test we are recommending requires a small droplet of blood from your finger in order to get a measure of your HbA1c; that is a measure of your blood glucose level over the last 2-3 months. A1CNow+® provides us with a fast and easy way of obtaining accurate A1C results rather than sending a blood sample for testing in a laboratory. This innovative technology mean we can tell you your result instantaneously.

(Delete as appropriate)

- You DECIDED to have the test:

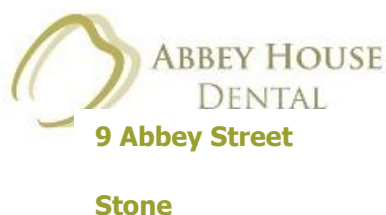
YOUR HbA1c RESULT IS:

A result of **6% or higher** suggests you may have diabetes. However, a result of **lower than 6%** suggests it is unlikely you have diabetes, HbA1c results **between 5.7% and 6.0%** suggest you may have pre-diabetes.

We RECOMMEND you visit your GP for a further diagnostic test to follow-up these initial screening tests.

.....
- You DECIDED NOT to have your HbA1c measured. However, we would RECOMMEND you still visit your GP for further testing based on the result of the FINDRISC.

More information about diabetes can be found on the UK's leading diabetes charity, Diabetes UK website: <http://www.diabetes.org.uk/>



Unit of Social and Behavioural Sciences
Floor 18 Tower Wing
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London
SE1 9RW

Letter to GP (low risk)

(Version 3, 08.05.13)

Date.....

Dear.....

Your patient.....(DOB-.....) has taken part in the following research study.

Study Title: The effects of screening for diabetes in the dental setting on subsequent health behaviours

REC Study Number: 13/WM/0265

We attach an Information Sheet for your records.

Your patient's scores on the Finnish Diabetes Risk questionnaire (FINDRISC) was Scores ≥ 10 indicate the risk of developing pre-diabetes and / or diabetes.

Based on their FINDRISC score carried out today, your patient has shown to be at low risk of developing diabetes or pre-diabetes in the next ten years.

This result has been explained to your patient.

Dr. Amit Jilka
(Dental Surgeon)

and

Miss Kathryn Bould
(Researcher)



9 Abbey Street

Stone

ST15 8PA



Unit of Social and Behavioural Sciences
Floor 18 Tower Wing
Guy's Hospital
London
SE1 9RW

Letter to GP (high risk)

(Version 3, 08.05.13)

Date.....

Dear.....

Your patient.....(DOB-) has taken part in the following research study.

Study Title: The effects of screening for diabetes in the dental setting on subsequent health behaviours

REC Study Number: 13/WM/0265

We attach an Information Sheet for your records.

Your patient's score on the Finnish Diabetes Risk questionnaire (FINDRISC) was Scores of ≥ 10 indicate the risk of developing pre-diabetes and/ or diabetes.

Your patient's instant HbA1c blood test information was.....(refused).

On the basis of these results which have been fully explained to your patient, they have been advised to attend your GP practice for further diabetes diagnostic testing if appropriate.

A handwritten signature in black ink, appearing to read 'Amit Jilka'.

Dr. Amit Jilka
(Dental Surgeon)

and

A handwritten signature in black ink, appearing to read 'Kathryn Bould'.

Miss Kathryn Bould
(Researcher)



9 Abbey Street

Stone

KING'S
College
LONDON

Unit of Social and Behavioural Sciences
Floor 18 Tower Wing
Guy's Hospital
London
SE1 9RW

Referral letter to GP (CES-D)

(Version 1, 09.05.13)

Dear.....

Your patient..... was recently seen by their dentist and took part in the following research study:

Study title: The effects of screening for diabetes in the dental setting on subsequent health behaviours.

REC study number: 13/WM/0265

Date of participation:.....

As part of the study, your patient completed the 'Centre for Epidemiological Studies Depression Scale' (CES-D). This is a screening measure (NOT a diagnostic tool) developed to identify current depressive symptomatology related to major or clinical depression in adults.

CES-D Score.....

(The range of scores on the CES-D is 0-60, with a cut off score of 16 indicative of "significant" or "mild" depressive symptomatology.)

I have informed the patient that I have written to you with this information and suggested that they make an appointment to see you.

Yours faithfully,

A handwritten signature in black ink, appearing to read 'Amit Jilka', with a stylized flourish at the end.

Dr. Amit Jilka
(Dental Surgeon)

and

A handwritten signature in black ink, appearing to read 'Kathryn Bould', written in a cursive style.

Miss Kathryn Bould
(Researcher)



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Referral letter to GP (HbA1c)

(Version 1, 13.05.13)

Dear.....

Your patient.....(DOB -.....) was recently seen by their dentist and took part in the following research study:

Study title: The effects of screening for diabetes in the dental setting on subsequent health behaviours.

REC study number: 13/WM/0265

Date of participation:.....

As part of the study, your patient received an instant finger-prick blood test to measure their HbA1c. We are using the Bayer A1c+ NOW kit to measure a patient's instant HbA1c level as a way of screening for diabetes.

HbA1c score.....%

I have informed the patient that I have written to you with this information and have suggested that they make an appointment to see you.

Yours faithfully,

A handwritten signature in black ink, appearing to read "Amit Jilka".

Dr. Amit Jilka
(Dental Surgeon)

and

A handwritten signature in black ink, appearing to read "Kathryn Bould".

Miss Kathryn Bould
(Researcher)

Appendix 19: Script for follow-up call to high risk patients

FOLLOW-UP PHONE CALL SCRIPT TO HIGH RISK PATIENTS

Hello.....

Its.....calling fromregarding the research study you took part in at your dental appointment at The Broadway Dental Practice in Catford last month.

Im just calling to ask you a couple of questions, this should only take a few minutes. Is now a convenient time to talk?

YES

NO

Great.

When we screened you for diabetes at your last dental appointment, based on your risk result, we advised you to go and see your GP for further tests for diabetes.

Can I ask, have you been and visited you GP based on this advice regarding your risk of diabetes?

Is there a more convenient time to call back?

Great, I shall call you

Thanks.

YES

NO

Ok,

What did the GP say or do?

Test result?

We just need to ask as well, if you've received any other invitations to go for screening or testing for diabetes since we advised you of your risk?

As well as going to see your GP, we are interested if you have made any other lifestyle changes since you screening tests results?

Thanks

Ok,

Well we do recommend you see your GP based on the result of the screening tests we carried out.

I will call you back in another month if that's ok, just to see how you've got on.

Thanks

CALL AT 2 MONTHS

Hello.....

Its.....calling fromregarding the research study you took part in at your dental appointment at The Broadway Dental Practice in Catford a few months ago.

I'm just calling to ask you a couple of questions; this should only take a few minutes. Is now a convenient time?

YES

NO

Great.

When we screened you for diabetes at your last dental appointment, based on your risk result, we advised you to go and see your GP for further tests for diabetes.

Can I ask, have you been and visited your GP based on this advice regarding your risk of diabetes?

Is there a more convenient time to call back?

Great, I shall call you

Thanks.

YES

NO

Ok,

What did the GP say or do?

Test result?

We just need to ask as well, if you've received any other invitations to go for screening or testing for diabetes since we advised you of your risk?

As well as going to see your GP, we are interested if you have made any other lifestyle changes since your screening tests results?

Thanks

Ok,

Well we do recommend you see your GP based on the result of the screening tests we carried out.

Thanks

SEND 3 MONTH FOLLOW UP GP LETTER TO ALL HIGH RISK PATIENTS



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London
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Follow-up Letter to GP

(Version 2, 03.05.13)

Date.....

Dear.....

Your patient.....(DOB -.....) has previously taken part in the following research study.

Study Title: The effects of screening for diabetes in the dental setting on subsequent health behaviours

REC Study Number: 13/WM/0265

We have previously written to you with the results of some initial diabetes screening tests that we conducted, and based on the results, we advised your patient to attend your GP practice for further diabetes diagnostic tests.

In order to keep our medical records up to date and to ensure we provide our patient with the best possible treatment, could you please advise us on the following:

Please tick all that apply:

☐

Patient has not been in contact with the GP practice for a diagnostic test.

☐

Patient has enquired about a diagnostic test but we felt it was not appropriate.

☐

Patient has received a diagnostic test.

The outcome was:

Please send this letter back in the pre-paid addressed envelope provided.

Yours,

A handwritten signature in black ink, appearing to be 'Amit Jilka'.

Dr. Amit Jilka
(Dental Surgeon)

And

A handwritten signature in black ink, appearing to be 'VJ Bould'.



Health Research Authority

National Research Ethics Service

NRES Committee West Midlands - The Black Country

HRA NRES Centre Manchester
3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7821
Facsimile: 0161 625 7299

31 July 2013

Dr Koula Asimakopoulou
Senior Lecturer / HPC- Registered Health Psychologist
King's College London
Unit of Social and Behavioural Sciences
Dental Institute, Caldecot Road, Denmark Hill
London
SE5 9RW

Dear Dr Asimakopoulou

Study title:	Screening for diabetes in dental settings
REC reference:	13/WM/0265
IRAS project ID:	122284

Thank you for your letter of 29 July 2013, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair and Dr Tony Zalin.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator, Miss Shehnaz Ishaq, nrescommittee.westmidlands-blackcountry@nhs.net

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).